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TASK FORCE ON PRESCRIPTION DRUGS

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TERMINOLOGY

The term *generic equivalents* is not used in the body of this report. Although it has been widely utilized, it has been given so many different interpretations that it has become confusing. Instead, the following terms are used:

Chemical equivalents—Those multiple-source drug products which contain essentially identical amounts of the identical active ingredients, in identical dosage forms, and which meet existing physicochemical standards in the official compendia.

Biological equivalents—Those chemical equivalents which, when administered in the same amounts, will provide essentially the same biological or physiological availability, as measured by blood levels, etc.

Clinical equivalents—Those chemical equivalents which, when administered in the same amounts, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease.

The following terms are also used:

Generic name—The *established* or *official* name given to a drug or drug product.

Brand name—The registered trademark name given to a specific drug product by its manufacturer.

INTRODUCTION

In May of 1967, acting upon a directive from the President, John W. Gardner—then Secretary of Health, Education, and Welfare—established the Task Force on Prescription Drugs. The charge to the Task Force appeared to be simple——

Undertake a comprehensive study of the problems of including the cost of prescription drugs under Medicare.

Few assignments, however, have been more complex. Essential for the Task Force study was objective information on the health needs and resources of the elderly; the present patterns of drug use; the nature of drug research, production, and distribution; current insurance programs in the United States and abroad; the pharmacological and clinical aspects, including the intricate problem of chemical and clinical equivalency of generic products; legal and fiscal aspects; and reimbursement methods and administrative approaches.

In some instances, the necessary data were readily available. In others, they were not—and the Task Force found it necessary to undertake its own special research projects.

The information derived from these studies serves as the basis for the findings and recommendations which are being published separately by the Task Force. In addition, however, this basic material appears to have great value for the Congress, many State and Federal governmental agencies, the medical and pharmacy communities, the drug industry, health insurance organizations, health educators, and consumer groups. Accordingly, the Task Force is publishing the detailed results of its studies in a series of background papers.

This volume, comprising studies on some of the chief elements involved in designing a drug insurance program, and presenting various alternatives for consideration in developing a program blueprint, is one such publication. It was prepared by the Task Force staff in cooperation with many consultants, both governmental and nongovernmental, whose invaluable assistance is gratefully ackowledged. Special appreciation goes to the staff members of the Social Security Administration and the Social and Rehabilitation Service, and to the many representatives of State and private drug insurance programs, the pharmaceutical industry, the pharmacy profession, and the medical and scientific communities who kindly made available much unpublished material to the Task Force and provided their valuable advice, guidance and proposals to the Task Force staff.

Particular gratitude is expressed to Dr. T. Donald Rucker of the Social Security Administration, who carried major responsibility for the preparation of this volume, and to Dr. Bradley Neer, of the Social and Rehabilitation Service, who headed the development of the new drug classification and coding programs.

Many of the issues considered in this background paper are complex, a few are disquieting, and the answers to most will come neither easily nor comfortably. There is little likelihood that all the solutions will be universally satisfactory to the drug industry, the pharmacy profession, the medical profession, governmental officials, the patients—and the taxpayers.

If an out-of-hospital prescription drug program is developed under Medicare, it will not only be the largest drug insurance program ever undertaken in the United States, but it will pose challenging problems to all segments of our health system.

One issue will concern the response of the drug industry to what may well be a very large increase in the demand for its products, together with a demand for ever higher quality and control of costs.

A second will involve the response of drug vendors, and a challenge to pharmacists to accept increasing responsibility as health professionals.

A third will involve the ability of governmental officials to utilize their imagination and their innovative skills in designing and operating a program that is aimed not primarily at providing administrative ease and simplicity, but at providing the maximum benefits and the highest quality of health care at the lowest practical administrative costs.

A fourth will involve the readiness of the Nation's physicians to accept responsibility for reviewing the manner in which they prescribe drugs for their patients, and—where necessary—to modify their own prescribing patterns, regardless of the pressures and blandishments to which they may be exposed—and to do this not simply to stem the rising costs of medical care but to improve the quality of the care. Perhaps no other single aspect of a drug insurance program will be so critical in determining the success or failure of that program.

It is our hope that this publication—like the other background papers of the Task Force—will not only serve as the basis for careful analysis and discussion, but will help to improve the quality of health care for all Americans.

Philip R. Lee

PHILIP R. LEE, M.D.

CHAPTER 1

THE MAKING OF A BLUEPRINT

The 19 million elderly men and women in the United States represent slightly less than 10 percent of the population, but their need for health care and notably for prescription drugs is far out of proportion to their numbers. These needs, coupled with the limited financial resources of the elderly, pose a problem that is causing serious and steadily increasing concern.

Drug Needs

In 1966, the elderly—those aged 65 or more—obtained some 225 million out-of-hospital prescription drugs at a cost of almost $900 million. These accounted for 22 percent of total out-of-hospital prescriptions and 25 percent of all costs for prescription drugs at the retail level.[1]

Earlier data, collected in 1964 and 1965 by the National Health Survey, indicate that the average number of prescription drug acquisitions—original prescriptions or refills—was nearly three times as great for the elderly as for those under the age of 65, while the average per capita expenditure for the elderly was more than three times as great.[2] For the elderly, as for the population as a whole, the National Health Survey data likewise show that average prescription drug expenditures were higher for women than for men, for whites than for nonwhites, and for those with serious chronic disease.[3]

The relation between chronic illness and high drug expenses is of significant importance. Thus, it is estimated that approximately 17 percent of the elderly suffer from heart disease, 16 percent from high blood pressure, and 7.5 percent from other cardiovascular diseases; 33 percent suffer from arthritis and rheumatism; and 10.5 percent have mental or nervous disorders.[4] The reported prevalence of these conditions appears to be closely associated with the drugs used by the elderly. These products have been examined by the Task Force in establishing the Master Drug List (MDL), which includes the 409 out-of-hospital prescription drugs most frequently dispensed to the elderly in 1966, and which account for 88 percent of all prescriptions dispensed to the elderly, and 88 percent of the total prescription costs at the retail level.[5] Among these MDL prescriptions, about one-half were for drugs commonly used in the treatment of heart disease, hypertension, arthritis, rheumatism, and mental and nervous conditions.[6]

Further evidence of the association between drug use and chronic illness is the finding that about one-fifth of the MDL products were dispensed in quantities for use for an average of 90 days or more in a year, and represented more than a third of total MDL costs to the elderly consumers.[7]

The MDL data are consistent with those collected by the National Health Survey in 1964–65. For instance, the 1964–65 figures show that for the relatively few elderly with no chronic disease, the annual per capita cost for prescribed drugs was $3.60 per year, representing the acquisition of an average of 1.2 prescriptions. For those with one or more chronic conditions, the number of acquisitions rose to 13.5 and the annual cost to $48.80. When the condition was sufficiently severe to limit major activity completely, acquisitions averaged 21.7 prescriptions, and costs averaged $78.80. In general, the data indicate that prescription expenses of those of the elderly with severe chronic illness—about 15 percent of all the elderly—were more than six times as great as the expenses of those below the age of 65.[8]

Financial Resources

Unfortunately, the elderly are characterized not only by higher than average health needs and drug expenses. They also have lower than average financial resources with which to meet those expenses. As of January 1, 1969, it is estimated that almost 5 million elderly persons were living in poor households, as measured by the Social Security Administration's poverty index. If elderly persons living in institutions and those with incomes below the poverty level living in households whose total income is above that level are also counted, then a little more than 7 million, or 36 percent, of the total elderly population were poor.

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[1] U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, pp. 16, 21.

[2] U.S. Public Health Service, National Center for Health Statistics: "Cost and Acquisition of Prescribed and Nonprescribed Medicines. United States—July 1964–June 1965," Series 10, No. 33, p. 24.

[3] *Ibid.*, pp. 24, 26, 28.

[4] "The Drug Users," *op. cit.*, p. 12.

[5] "The Drug Users," *op. cit.*, p. 31 *et seq.*

[6] *Ibid.*, p. 35.

[7] *Ibid.*

[8] "Cost and Acquisition of Prescribed and Nonprescribed Medicines, *op. cit.*, p. 28.

Among social security beneficiaries, although benefit income kept some 6.8 million out of poverty, another 5.8 million, or 36 percent, remained poor. An additional 3 million were in the near-poor group, and only a little better off.[a]

To help meet their drug expenses, the elderly were able to obtain only limited assistance from private health insurance, public assistance programs, free drugs given by physicians, and Federal tax relief. Together, these four potential sources covered only about 20 percent of their costs.[9]

Available data therefore indicate that the elderly use significantly more prescription drugs than do younger Americans, and that those of the elderly who suffer from serious chronic illness have significantly higher total drug expenses than those who are not so afflicted.

The data also show that the elderly in general have relatively limited incomes and assets, and that only a small proportion of their drug expenses for out-of-hospital drugs is met through private insurance, public assistance programs, free drugs from physicians, and tax relief.

The situation with out-of-hospital prescription drugs, as noted above, is strikingly different from that with inhospital drugs, which are covered to a substantial degree by the present Part A (Hospital Insurance) program under Medicare. For a hospitalized Medicare patient, the cost of necessary drugs is no longer a significant problem; a physician can prescribe for such a patient as his clinical needs require, and without any appreciable consideration of the patient's financial status. It seems reasonable to presume that this inhospital approach not only helps to conserve a patient's funds but also removes economic barriers to appropriate health care.

It may also be reasonable to presume that the same goals—protecting elderly patients from heavy drug expenses and improving the quality of health care—may be achieved for out-of-hospital patients by extending the Medicare program to cover out-of-hospital prescription drugs.

Blueprint for a Program

The design of a suitable out-of-hospital prescription drug program for the elderly requires first a consideration of the major underlying aspects of the situation—the needs, resources, and other characteristics of the elderly; the nature of private and governmental drug programs currently underway in the United States and other countries; the nature of the pharmaceutical industry, including its pricing structure, research, promotional activities and profits; the nature of the drug distributing system; and the prescribing patterns of physicians, the sources of information available to them, and the relative quality and prices of drugs.

These aspects have been considered by the Task Force in other background papers.[10–13]

Finally—and in many cases based on the findings from the other Task Force studies—it is necessary to consider the basic aspects of the drug insurance program itself, and to examine the various approaches to a program design. Among the major aspects are these:

- The relative advantages of providing comprehensive coverage or a less-than-comprehensive program based on limited drugs, limited beneficiary eligibility, or various cost-sharing methods.
- The relative advantages of providing major program financing through Part A (the social insurance approach) or Part B (the premium approach) of Medicare.
- The advantages of reimbursing the patient or the pharmacist.
- The relative advantages of a variety of approaches for reimbursing for product cost and for dispensing services.

---

[a] The poverty line used was $1,500 for a single individual and $1,900 for a couple, applied to 1968 income. The low income (near-poor) line was defined as incomes of $1,800 and $2,600, respectively.

[9] "The Drug Users," *op. cit.*, p. 27.

[10] "The Drug Users," *op. cit.*

[11] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968.

[12] Task Force on Prescription Drugs: "The Drug Makers and the Drug Distributors," *ibid.*

[13] Task Force on Prescription Drugs: "The Drug Prescribers," *ibid.*

- The advantages of a variety of cost-sharing techniques, including deductibles, co-insurance, and co-payment, used alone or in combination.
- The value of various data requirements, regulations, and other administrative aspects.
- The value of appropriate classification and coding techniques needed for automated data processing.
- The potential strategic importance of utilization review.
- Estimates of probable costs based on various approaches and assumptions.

It is quite apparent that all these aspects cannot be viewed as separate and unrelated. Many and probably most of them are intimately related, and a decision to select one particular approach to solve one particular problem will inevitably influence decisions involved with other problems. For example, any determination to provide direct patient reimbursement would almost certainly influence the selection of appropriate cost-sharing methods. A determination to require a large annual deductible would probably require direct patient reimbursement. A decision to provide coverage under Part B rather than Part A would involve important specifications for establishing patient eligibility through the data processing system.

It is also evident that the decisions required for establishing the program design could be based on such factors as satisfying primarily the patients, or the physician, or the drug maker, or the drug distributor, or the program administrator, or especially the taxpayer. It appears, however, that other goals might well be given higher priority—

- The program, above all, should be aimed at improving health care for the elderly.
- It should be designed in such a way as to reduce the heavy financial burden of drug costs on the elderly.
- It should not inflate drug costs either to the program itself or to the general public.
- It should be readily integrated with existing systems of health care delivery, including other insurance programs and Federal and State medical assistance programs.
- It should encompass optimal quality and cost controls and efficient administrative methods that may serve as models for other health insurance, medical assistance, and medical care programs.
- It should promote rational drug therapy, not only for the elderly but for all patients.
- It should be easily understandable to beneficiaries, vendors, physicians, and taxpayers.
- It should encourage efficiency in drug manufacturing, distribution, and dispensing.
- It should discourage waste of resources—including manpower resources—and commercial practices which add to costs without proportionately increasing the value of the service.
- It should provide the designated program administrator with adequate financial and administrative responsibility and authority to prevent needless cost inflation and program abuse.

These and other objectives are important in consideration of the various aspects of drug insurance design that are discussed in the following chapters of this volume. It will be apparent that the attainment of most of the goals will require the most careful evaluation, experimentation and analysis.

CHAPTER 2

SCOPE OF BENEFITS

Coverage of out-of-hospital prescription drugs under Medicare would obviously relieve the elderly of part of the economic burden associated with their high drug costs, and would also represent an important step in assuring that their total health care needs are adequately met.

To the greatest extent possible, a Medicare drug program should be designed in such a way that beneficiaries will be able to understand it easily and will not be unduly burdened by the procedures for obtaining benefits, and that administrative costs will be kept within reasonable limits. In the event that funds are inadequate to support a full-scale, comprehensive program, consideration may be given to techniques for reducing the program benefits as a means of limiting program costs.

One of the most important considerations affecting such factors is the scope of the drug benefits to be provided. Here attention will be directed particularly to (1) the nature of drugs to be covered in the program, (2) the characteristics of the program beneficiaries, and (3) the cost-sharing methods applied to limit program expenditures.

Drug Coverage

Drugs on the market may be classified generally in two ways—*over-the-counter* drugs (OTC's), which are available without prescription, and *legend* drugs, which can be obtained legally only with a prescription from a physician or other licensed practitioner; or *nonprescribed* drugs, which a patient gets without a prescription, and *prescribed* drugs, which are obtained with a prescription and which can include both OTC's and legend drugs.

There seems to be wide agreement that a drug insurance program should properly cover only prescribed medications. This is based on the facts that such drugs will have been ordered on the basis of a medical review of the patient's condition, that they are the ones most likely to require major financial outlays by the patient, and that insurance coverage for most nonprescribed medications would probably be an administrative and fiscal impossibility.

Whether or not the program should cover all prescribed drugs—legend and nonlegend products alike—is a somewhat more complex matter. In a program for the elderly, exclusion of prescribed nonlegend drugs from coverage is likely to reduce the number of claims by about 10 percent and the dollar value of benefits by less than 8 percent.[a] Such a restriction would also have the effect of preventing a physician from writing a prescription for aspirin, diet supplements and other OTC's simply to save money for his patient.

Confining drug benefits to legend drugs, however, would have certain disadvantages. The administrator can expect claim review expenses to rise as he attempts to determine whether a particular prescription is actually covered under the program. Despite specific exclusions for OTC items, some carriers have found it less costly to pay for all prescriptions submitted for reimbursement than to conduct the necessary eligibility checks. (The cost of such checks and reviews can be readily minimized by use of an appropriate automated data processing system.)

In addition, this limitation would present a problem to those physicians who may be unaware of the legal status of all the drugs they prescribe, and accordingly they may be required to ascertain whether or not a particular product is covered under the program. This distinction, moreover, may be logical from a legal point of view but not on medical grounds. Thus, a physician writes a prescription because he wishes the patient to take the medication. Since the prescription is related—on medical grounds—to anticipated benefits from the drug, insurance coverage limited to legend products creates a distinction that is arbitrary.

Nevertheless, most proposals for drug coverage under Medicare have specified mainly prescribed legend drugs, with inclusion perhaps of a few nonlegend drugs such as insulin. This approach is considered here as *comprehensive drug coverage.* Most of the legislative proposals for coverage that have been introduced in the Congress thus far would have covered drugs on this comprehensive basis—that is, they would have covered the majority of the approximately 1,200 different legend drugs on the market.

---

[a] Based on estimates by the Social Security Administration, January 1969.

It should be noted, however, that so-called comprehensive coverage does not necessarily imply coverage of all prescription drugs. Even programs providing the most nearly complete coverage have limits on the drugs covered and establish limiting conditions under which payment for drugs is made. For example, it is the common practice of many insurance and other drug programs to exclude from coverage certain classes of drugs—e.g., anti-obesity drugs, multiple vitamins, nonnarcotic sedatives, antacids, etc.—whose medical necessity is often considered marginal.[1] Other programs exclude contraceptives. Still others exclude drugs such as those used for the treatment of venereal disease, tuberculosis or mental disease which may be available at no cost from a local or State health agency. Finally, some programs exclude tranquilizers and other agents for the control of mental illness unless the patient has previously been treated in a mental hospital.

Even with the exclusion of such drugs from coverage, the numerous and complex administrative problems and very high program costs that could be involved in covering the remaining legend drugs present strong arguments for considering less-than-comprehensive coverage, at least in the first stages of a new drug program under Medicare.

Administrative Problems

One important consideration in developing a plan for the coverage of drug expenses of the elderly is the extremely large volume of bills for covered services which would be involved if comprehensive coverage were provided.

- It is estimated that the elderly would obtain more than 300 million prescriptions in the first year of operation.[a]
- These prescriptions would be obtained through some 54,000 community pharmacies and some 3,000 hospital outpatient departments, as well as other providers of drugs to outpatients (e.g., mail-order firms, extended care facilities, clinics, and dispensing physicians.)

The magnitude of the administrative tasks implied by these figures can be appreciated by comparing them to operating statistics for the first year of Medicare:

- During fiscal year 1967, some 10.4 million claims were processed by the hospital insurance intermediaries, while 26.5 million claims were processed under the medical insurance part of the program—a total of less than 37 million claims.
- The covered services were provided by about 7,000 participating hospitals, 4,000 extended care facilities, 2,000 home health agencies, 2,000 independent laboratories, and more than 170,000 physicians.

Even though the pharmacists and other drug vendors submitted combined or composite bills for covered drugs, the volume of items to be processed under a comprehensive program would obviously be much greater than that under the present Medicare program. While the claims process would be fairly uniform and simple, it appears that each claim would entail a minimum of half a dozen items of information,[b] all of them subject to transcribing errors.

Under these conditions, it is clear that efficient administration of a drug program of such magnitude requires a fully automated data processing system operating with a high degree of accuracy. The development of such a system can be expected to involve a number of technical problems; and while these would gradually diminish with time and experience, it may be essential at the outset to limit the number of claims to a volume at which the technical risks would be minimal. And even under a limited drug coverage program, a considerable lead time would be required to develop efficient administrative methods.

On the other hand, it may be preferable to consider that once an appropriate data processing system is developed, it could handle 300 million or more claims per year as readily as it could handle 50 or 100 million, and thus the capability of the system should not be viewed as a major reason for limiting coverage. With such a high capability system, of course, technical problems can also be expected, and would require appropriate advance planning and testing.

An additional consideration is that a large proportion of prescriptions are relatively inexpensive. Under these circumstances, it is difficult but important to develop provisions for administration so that costs associated with claims processing would not be excessively high in proportion to the benefits received by the beneficiary.

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[1] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968, *passim*.

[a] Estimates of persons covered, benefit costs and administrative costs are given in Chapter 9 and Appendix A. The estimates are based on a 1971 effective date.

[b] See pp. 43 *et seq.*

A final factor is that there is only limited useful precedent in either private insurance or governmental drug programs from which to develop the administrative procedures needed if a comprehensive drug benefit of this magnitude were provided.[2]

Cost of Comprehensive Coverage

Another important point relating to coverage of most of the prescription drug expenses of the elderly under Medicare is the high cost associated with such coverage. An estimate based on one set of assumptions indicates that the cost of comprehensive coverage would be $660 million, exclusive of administrative costs. (This estimate assumes a $1.00 co-payment per prescription, an effective date of 1971, a per capita acquisition of 14 prescriptions per year, and an average price per acquisition of $3.30.) [a]

On the other hand, using quite different assumptions, the Social Security Administration has indicated that the "high-cost" estimate [b] for comprehensive coverage of prescription drugs under Medicare, with a 20-percent co-insurance and an effective date of 1971, would be $1.6 billion, exclusive of administrative costs. (This estimate assumes a per capita acquisition of 21.5 prescriptions, and an average price per acquisition of $4.58.)

The Case for Less-than-Comprehensive Coverage

There are, then, sound reasons why, in the first stages of administering a drug program, the Medicare program should not attempt to meet virtually all of the drug expenses of all older people. In face, there is some question whether it would ever be desirable to attempt to provide insurance protection against small annual drug expenditures. A more efficient use of program funds might result if an effective system could be found for limiting the benefits in a way that would concentrate the protection where it is most clearly needed.

Approaches to Limited Coverage

Several possible methods of less-than-comprehensive coverage may be considered. Among them are these:

- Coverage of only those drugs important for the treatment of serious chronic illnesses which afflict the elderly—notably the so-called maintenance drugs.
- Coverage of most prescription drugs, but with eligibility for the drug benefit restricted to social security beneficiaries who have attained age 70 or, alternatively, age 72.

These two approaches are examined in the following sections. In addition, there are other techniques which would contribute to limiting program costs, and which could be used alone or in combination with other methods. Among them are the following:

- Coverage of most prescription drugs, combined with the use of a relatively large annual deductible applicable to drug expenses.
- Setting maximum limits on the cost of prescriptions to be reimbursed.
- Setting maximum limits on the quantity of a drug per single prescription for which reimbursement would be made.
- Discouraging over-utilization through the use of such cost-sharing mechanisms as co-payment or co-insurance applied to each prescription.

These techniques are discussed in Chapter 5. In addition, the value of utilization review in limiting over-utilization is considered in Chapter 8.

Finally, costs could be reduced by restricting coverage to those products listed in a scientifically designed formulary. The use of such a formulary is discussed elsewhere.[c] [3]

Coverage of Maintenance Drugs

In another study, 27 different diagnostic categories have been identified, headed by heart disease, high blood pressure, arthritis and rheumatism, and mental and nervous conditions, for which drug therapy is widely used.[4] Similarly, the most frequently dispsensed drugs have been classified into 32 different therapeutic categories ranging from amebicides to vitamins.[5]

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[2] "Current American and Foreign Programs," *op. cit.*, *passim.*

[a] The basis for this estimate is shown in Chapter 9.

[b] The "low-cost" estimate for comprehensive coverage of prescription drugs, and the assumptions on which these estimates are based, are outlined in Appendix A.

[c] See pp. 69–70.

[3] Task Force on Prescription Drugs: "The Drug Prescribers," U.S. Government Printing Office, Washington, D.C., 1968, pp. 12–13, 43–50.

[4] Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, pp. 34–35.

Under an insurance program, it is feasible to select a limited number of these diagnostic or therapeutic categories and pay only for those prescriptions which belong in the appropriate group.

For such an approach, consideration has been given to coverage of only those drugs which are used for the treatment of "serious" diseases, "chronic" diseases, "life-threatening" conditions, "disabling" diseases, or such a grouping as heart disease, cancer and stroke. In the same way, coverage could be limited to those drugs which, for example, are classified as cardiovascular agents, antiarthritics, tranquilizers, psychostimulants, antibiotics, etc.

Available data on drug use support the hypothesis that coverage of only those drugs which are important for the treatment of chronic illness among the elderly, and which usually are required on a continuing or recurring basis, would concentrate the protection provided by a drug program where in most cases it is most clearly needed.[6]

There is clearly wide variation among the elderly in the extent to which they use prescription drugs. Those older people who have serious chronic illnesses use more drugs than those who are not chronically ill,[7] and many of the drugs most frequently used by the elderly are associated with the serious chronic illnesses which afflict them.[8]

If coverage were to be limited to selected maintenance drugs required in the treatment of chronic illness, the Medicare law could provide that the Secretary of Health, Education, and Welfare would establish the list of specific drugs to be covered under the program. He would select those drugs that he finds are important in the treatment of the many serious chronic conditions afflicting the elderly. Once a drug was so specified as a covered drug, reimbursement could be made without regard to the condition for which it was prescribed. The law might include guidelines indicating how the list would be established. Also, to assist the Secretary in establishing the list of covered drugs, the law might provide for an Advisory Council on Drugs, including nongovernmental experts in pharmacology, pharmacy, geriatrics and other branches of clinical medicine, and representatives of consumer groups.

The statutory guidelines on the selection of drugs to be covered could authorize the Secretary to consider whether, both absolutely and in relation to other drugs in its therapeutic class, a drug was (1) of acceptable quality; (2) safe and efficacious, giving careful consideration to relative toxicity and taking into account studies by the Department of Health, Education, and Welfare, the Department of Defense, the Veterans Administration, and other agencies which the Secretary found to be appropriate; and (3) not unduly expensive in relation to its therapeutic efficacy.

The drugs selected could include—in addition to drugs which can only be dispensed upon prescription by physicians—certain drugs which can be dispensed without a prescription (e.g., insulin), but only if the Secretary found that such drugs were "lifesaving drugs," or that their withdrawal would be seriously harmful to individuals who had been using them, or that they provided acceptable substitutes in terms of economy and effectiveness for other drugs included in the list.

The guidelines could require that the list be reviewed and revised as necessary, at least once each year, and that the Secretary be required to report to the Congress annually on the adequacy of the list and the cost of the drug benefits being paid.

If such an approach were adopted, it may be estimated that the level cost of the new benefit, if provided under Part A of the Medicare program and assuming a $1.00 co-payment, would be 0.19 percent of taxable payroll. Here it is assumed that benefit payments would amount to $714 million, representing about 210 million claims.[a] Using a different set of assumptions, including a much higher average prescription price,[b] it has been estimated that the level cost, again using a $1.00 co-payment, would also be 0.19 percent of taxable payroll (estimated on a "high-cost" basis and exclusive of administrative costs), with reimbursement made for about 135 million prescriptions.

A more limited approach would be the restriction of coverage to drugs which are important in the treatment of a limited number of specific, serious chronic conditions: for example, the list of covered drugs might be limited to those which are important in the treatment of cardiovascular disease, diabetes, kidney conditions and respiratory conditions. Such an approach would involve somewhat lower workloads and benefit costs than would be concerned in coverage of drugs important in the treatment of virtually all the chronic conditions of the elderly.

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[5] *Ibid.*, pp. 33, 35.

[6] *Ibid.*, p. 35.

[7] *Ibid.*, p. 24.

[8] *Ibid.*, Table 31, p. 32.

[a] See Chapter 9.

[b] See Appendix A. It should be noted that the level-cost estimates given throughout the text do not include administrative costs. A range of administrative costs has been estimated and is discussed in Chapter 9 and Appendix A.

Coverage of such a limited number of drugs appears to be one of the most promising methods of providing limited drug coverage. It would have the administrative advantages of limiting the number of claims submitted for processing, and of providing the most protection to those of the elderly who, because they have recurring needs for drugs associated with chronic illness, can be assumed to have the greatest need for such benefits.

There are, however, certain disadvantages associated with this and similar approaches which warrant consideration. Some confusion may exist among patients, pharmacists and physicians about precisely which drugs are covered by the program and which are excluded. This would be particularly serious if vendor payment rather than patient payment were involved. Some patients would find that they could obtain none or only some of their prescription drugs through the insurance program, and therefore might conceivably have an incentive to seek hospital treatment—with the attendant higher costs—to overcome the restrictions. Some physicians and patients might bring pressure upon pharmacists to fill a noncovered prescription and charge the insurance program for some drug which is covered. Efforts to achieve rational drug prescribing through utilization review would be minimized because of a distorted data base and incomplete information on physician-prescribing and patient-consumption patterns.

It may be noted, however, that such countries as Norway and Denmark have found it feasible to cover only a limited number of specific drugs for the treatment of chronic illness, and have adopted this approach under their social insurance health care systems.[9]

In this country, a similar approach has been used successfully by the drug program of the United Mine Workers Welfare and Retirement Fund; in 1967 this program provided drugs for 500,000 eligible beneficiaries.[10] (The closed-panel United Mine Workers program is organized on a regional basis, with each region establishing its own formulary; the number of drugs in these formularies ranges from 64 to 148. Prescriptions are covered under the program only if they are obtained from physicians who have entered into participating agreements with the plan.)

A more fundamental possible drawback to this approach is whether widespread medical agreement can be reached on the drugs to be selected. Although it would, of course, be impractical to compile a final list of "covered" drugs far in advance of the effective date of drug coverage, continuing work could be done to develop lists of drugs in the therapeutic categories associated with treatment of chronic illness.

One question that needs to be explored in depth is whether a medically acceptable list of important drugs used in the treatment of chronic illness would include a disproportionately large number of drugs that are often used in the treatment of *both* chronic and acute illnesses, and whether a significant portion of benefits might therefore go for prescriptions to treat acute, short-term illness.

As indicated earlier, data from the Master Drug List indicate that a relatively small number of drugs account for a high proportion of the prescription drugs used by elderly individuals.[11] Although the Master Drug List provides merely an index of recent prescribing patterns, and does not necessarily reflect expert medical judgments as to what is good drug therapy or what drugs are most significant for treatment of serious illness, it serves at least as a guide to the number of frequently dispensed legend drugs in the various therapeutic categories associated with the continuing or recurrent treatment of the important chronic illness of the aged. The Master Drug List data indicate that there are fewer than 200 such drugs which are relatively frequently used for such purposes. It must be recognized, of course, that some infrequently prescribed drugs may involve very high expenses to some patients.

Pay Benefits At Age 70 or 72

Another approach to providing a limited drug benefit under Medicare which would also reduce the cost and the number of claims involved would be restricting the number of eligible beneficiaries, such as by making the benefit available only to those who attain a certain age—for example, age 70 or age 72.

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[9] "Current American and Foreign Programs," *op. cit.*, pp. 169, 187.

[10] *Ibid.*, pp. 127–28.

[11] "The Drug Users," *op. cit.*, pp. 31–34.

Under this approach, payment might be made for the great majority of the 1,200 different legend drugs on the market, offering the benefits of a comprehensive program although to only a limited portion of the elderly. Only 65 percent of the present population age 65 and over are 70 or older, and would therefore be eligible for benefits (53 percent would qualify if the eligibility age were 72).

On the basis of one set of assumptions,[a] if the eligibility age were set at 70 and virtually all prescription drugs were covered, the cost of the benefit—assuming a $1.00 co-payment—would be about $600 million in the first year of operation, and the level-cost of the benefit would be 0.23 percent of taxable payroll. If the eligibility age were set at 72, benefit costs would be about $500 million, and the level-cost would be 0.19 percent of taxable payroll. Reimbursement would be made for about 216 million claims if the eligibility age were 70, and 181 million if the age were 72. Costs and claims levels could, of course, be reduced further by means of cost-sharing provisions.[b]

On the basis of a different set of assumptions,[c] if the eligibility age were set at 70 and virtually all prescription drugs were covered, the level-cost of the benefit—again assuming a $1.00 co-payment—would be about $1.2 billion, requiring 0.42 percent of taxable payroll (estimated on a "high-cost" basis). If the eligibility age were 72, benefit costs would be about $1 billion, requiring 0.36 percent of taxable payroll. About 240 million claims would be involved with eligibility set at age 70, and 205 million if it were set at 72.

In general, it appears, both claims volume and program costs would be reduced about 30 to 40 percent through this approach.

Apart from the problem of rationalizing 70 or 72 as the age at which a particular Medicare benefit would become available when all other Medicare benefits are available at age 65, there is a question of whether such a new age limit would be the most effective means of concentrating protection where it is most needed. Medicare beneficiaries under age 70 or 72 who had very high drug costs might well have difficulty understanding a rationale which excluded them from coverage while paying for the drug expenses of people who, while older, might be in better health.

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[a] See Chapter 9.

[b] See Chapter 5.

[c] See Appendix A.

CHAPTER 3

PROGRAM FINANCING

Out-of-hospital prescription drug insurance for the elderly under social security could be funded in several ways—through contributions under the social insurance system (Part A of Medicare), through premiums paid by beneficiaries who elect to participate, as under Supplementary Medical Insurance (Part B), or through a new and separate Medicare approach (a hypothetical "Part X").

Under any of these methods, the contributions of the Federal Government could be lessened by employing one or more cost-sharing or other cost-reduction techniques which are discussed in Chapter 5.

The Social Insurance Approach (Part A of Medicare)

The hospital insurance and related benefits now furnished for virtually all of the elderly under Medicare are provided through Part A of Title XVIII of the Social Security Act. These benefits—along with old-age, survivors, and disability protection—are financed by a payroll tax which is currently 8.8 percent of creditable earnings,[a] and which will rise to 9.6 percent in 1970, 11.3 percent in 1975, and 11.8 percent in 1987.

Eligibility. If out-of-hospital drugs were covered under Part A of Medicare, virtually all people now aged 65 or more would be automatically eligible for the new benefit. As of July 1, 1968, 19.7 million persons aged 65 or more—99 percent of the elderly—were eligible for hospital insurance under Medicare, including some 2 million individuals who were not insured for social security or railroad retirement cash benefits but who were eligible for hospital insurance under a special "transitional" provision which is financed out of general revenues.

For men who attain age 65 after 1974—1973 for women—the special eligibility requirements provided under the transitional provision will merge with the regular requirements for social security benefits. Individuals who are not eligible for benefits under the transitional provision include retired or active Federal employees and their spouses who are eligible for health insurance coverage under the Federal Employees Health Benefits Act of 1959 and who are not eligible for monthly cash benefits under social security or the railroad retirement program, and certain aliens who have been in this country for only a short time.

It is expected that when the social security program is fully mature, from 95 to 98 percent of all the elderly will be eligible for hospital insurance benefits; ineligible persons will be only those who are not entited to monthly cash benefits under social security or the railroad retirement program.[b]

With this approach, establishment of eligibility would present minimal problems. Any individual eligible for hospital insurance or other benefits under Part A would also be eligible for the rest of his life for out-of-hospital drug benefits. He would have in effect a paid-up drug insurance policy when he reached the age of 65.

Financing. If a drug benefit were provided under Part A, the program would be financed through the regular contributory mechanism now used to finance hospital costs and the cash-benefit part of social security. Under such an approach, an individual would pay for this protection during his working years, rather than at a time of life when he may well have low income, limited assets, and high health costs. In addition, increases in the health costs and the utilization of services covered under Part A can be assumed in establishing the contribution rates and thus averaged and paid for over a substantial period of time. Also, with contributions based on earnings, increases in the general earnings levels that can be expected to occur in the future will automatically provide additional income to the system to help meet increases in health costs.

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[a] Creditable earnings are receipts from wage or salary income in specified occupations subject to the maximum taxable earnings ceiling established by law. The limit is currently set at $7,800 per year.

[b] The uninsured will include, in addition to active or retired Federal employees (and their spouses) and aliens, persons whose only employment was in State and local positions which remain outside social security; ministers, Christian Science practitioners, or members of religious orders who have not taken vows of poverty and who have elected not to be covered under social security, and members of religious orders who have taken a vow of poverty and are specifically excluded from coverage; and employees of nonprofit organizations who are eligible for coverage under voluntary arrangements but have not elected coverage. Other minor exclusions include persons whose earnings were so low or sporadic that they never became insured, and women who have not worked long enough to be insured on their own account and who cannot qualify for dependents' benefits.

The additional premium needed to finance a drug program under Part A would, of course, depend on the nature of the program—including the use of a comprehensive or a less-than-comprehensive coverage, cost-sharing method, and the like. As an example, it may be noted that under one approach,[a] a $1.3 billion program providing full service benefits and no cost-sharing would require an increase in payroll tax contributions of 0.4 percent—0.2 percent by the employer and 0.2 percent by the employee. With a $1.00 co-payment, the total increase would be 0.3 percent. With either a $2.00 co-payment or a $50 deductible, the total increase would be 0.2 percent.[b] Contributions could likewise be reduced by implementation of a less-than-comprehensive program, such as one providing coverage for only selected maintenance drugs.

The Premium Payment Approach (Part B of Medicare)

Under Part B of Title XVIII, the Medicare system now provides that eligible individuals aged 65 and over may elect to obtain insurance for out-of-hospital physician services. The beneficiary's share of the premium for this voluntary insurance currently is $4.00 per month, with the Federal Government matching this premium on a 1-to-1 basis from general tax revenues.

Participation depends at least in large part on an individual's ability to pay the monthly premiums.

Eligibility. As of July 1, 1968, 18.6 million people aged 65 or over—95 percent of the elderly—were enrolled under Part B of the Medicare program. It is clear that most of the elderly feel they need the protection that Part B offers, and it is expected that a high proportion of them will continue to participate in this voluntary part of the program.[c] Nonetheless, while some of the elderly who have not enrolled under Part B either feel they do not need or do not want the protection offered by the program, it is likely that many who have not enrolled simply cannot afford the monthly premium. There is, of course, no way to predict what effect future increases in the Part B premium will have on enrollement under that plan.

Another important consideration is that Part B eligibility lapses if the beneficiary elects to withdraw from the plan or if he fails to pay the monthly premium, while eligibility under Part A continues until a person's death. The experience of Title XIX drug programs indicates that the process of determining eligibility for benefits under a program in which continuing eligibility cannot be assumed constitutes one of the most expensive and troublesome parts of the claims process.[1]

Financing. If a drug benefit were provided under Part B of Medicare, the program would be financed through the monthly premiums paid by beneficiaries, and the matching government contribution paid out of general revenues. For example, a possible $1.3 billion program would require the present $4.00 monthly premium for each participating beneficiary to be increased by approximately $2.75, with a similar increase needed in the matching government contribution.[d] These increases could be minimized by the use of various cost-sharing methods.

This method of financing the drug benefit would have evident drawbacks. For example, the additional premium might prove sufficiently burdensome for the elderly who have to pay the present monthly premium, so that more of them might decide to reject any coverage under Part B. In this connection, it may be noted that, in 1966, 53 percent of the elderly individuals in this country, together with 11 percent of the families in which the head was aged 65 or over, had an income of less than $120 a month, while 29 percent of all elderly individuals, and 30 percent of the families in which the head was aged 65 or over, had an income of between $120 and $240 a month.[2] Many of these persons might find even a small increase in their monthly premiums would be a significant amount to pay from their low incomes. In addition, the insured person would also be responsible for the $50 annual deductible and a 20-percent co-insurance for covered medical services other than drugs, and any amounts in excess of the "allowable drug expense," if an indemnity program were established. Similarly, he would be responsible for any incurred health costs not covered under the Medicare program.

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[a] See Chapter 9.

[b] The percentage increase in the tax rate could be reduced, or bypassed entirely, by increasing the earnings base from $7,800 to a level necessary to raise the required revenue for drug insurance.

[c] In the fall of 1967, people whose premiums were deducted from social security, railroad retirement or Federal civil service retirement checks—the vast majority of enrollees—had their first opportunity to withdraw from the program. There were only about 35,000 withdrawals, and during the "general enrollment period" nearly 700,000 people enrolled who had failed to take advantage of their first opportunity to participate in the program.

[1] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968, pp. 51, 68.

[d] See Chapter 9.

An additional consideration is that, under Part B, increases in health costs or substantial increases in utilization of covered services must be paid for, through increases in the beneficiary's monthly premium, on a year-to-year basis as the cost increases occur.

In order to minimize the possibility of adverse selection, it would be necessary for drug insurance and physician insurance to be offered as a single package—that is, the patient would be required to purchase coverage of both drug and physician benefits or neither.

Under the premium approach, neither the program *per se* nor a formulary could properly limit coverage to maintenance drugs or any similar restrictive category. Since an individual's chronic ailments are largely known by the time he reaches the age of 65, those without such conditions would be unlikely to pay a full premium for what is clearly limited drug coverage. If the scope of benefits were actually restricted to maintenance drugs, a considerable proportion of the elderly would be required to contribute monthly premiums in the face of a very low probability of utilization.

Separate Drug Program ("Part X" of Medicare)

Consideration has been given to establishing a drug program as a separate operation of the social security system, possibly under a hypothetical "Part X" of Title XVIII. This would appear to offer no significant advantages other than providing greater visibility to the program.

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[2] U.S. Bureau of the Census: "Income in 1966 of Families and Persons in the United States," *Current Population Reports* (Consumer Income), Series P.60, No. 53, December 28, 1967, p. 24.

CHAPTER 4

REIMBURSEMENT

Under a drug insurance program, development of a reimbursement policy requires consideration of a number of major issues. Among these are selection of an appropriate payee option, and the construction of a reimbursement formula covering both the cost of the drug product and the cost of dispensing it to the patient. Various aspects are considered below.

PAYEE ALTERNATIVES

Patient Reimbursement

Reimbursement directly to the patient for part of his expenditures is characteristic of many so-called major-medical insurance plans, including those which provide prescription drug coverage. It could be considered for any government insurance program, and is actually used in the national drug program in France.[1]

One argument for this approach is that it would encourage greater interest on the part of the beneficiaries in the program and perhaps encourage greater efficiency among drug vendors as well. The patient, it is suggested, would be more aware of drug costs if he is required to pay for the prescription when he receives it, and this cost-awareness might motivate him to question high prescription prices, shop for lower priced outlets, and thereby lead to increased efficiency among dispensing outlets. In the same manner, it is hoped that the patient might try to persuade the physician to prescribe lower cost drug products where these are available and appropriate.

The cost control effect, however, might be more theoretical than real. The lack of knowledge about drugs and the immediate need for the medication in many instances would prevent the patient from pressing for lower drug costs. Many of the elderly would find it impossible, either because of health or transportation difficulties, to shop for low drug prices—as for low prices for any other commodity. The legal prohibition widely placed on pharmacists to prevent them from dispensing a lower-priced, high-quality product instead of a higher-priced identical product under a different brand name[2] would further limit the patient's ability to effect changes in vendor or manufacturer pricing patterns.

Under a patient reimbursement system, many of those eligible for payment would not file a claim, considering the necessary paper work more trouble than justified by a relatively small payment. Others—particularly elderly beneficiaries—might lose receipts or forget to file claims for all their purchases. As a result, aggregate benefit payments would probably be lower—perhaps 10 percent less—under a patient reimbursement system than under a system which paid vendors for all reimbursable prescriptions filled.

Experience with Part B of Medicare has shown the difficulties encountered when the elderly are required to submit claim forms.

In addition, some beneficiaries would forego needed drug therapy because they did not have the necessary funds available to make the purchases. While drug program expenditures would thus be reduced, the quality of health care would suffer and costs in other parts of the Medicare program could well increase as a result of increased physician and hospital services required.

A patient reimbursement system would result in high administrative expenses compared to a vendor plan unless payments were made only infrequently. In a Medicare program involving perhaps 50,000 drug vendor outlets and some 20 million potential users of drug benefits, it would probably be impossible to pay patients promptly when 250 to 300 million claims must be processed annually. Infrequent payments would be required, but these would limit the value of a drug insurance program to the beneficiaries, since the time lag between purchase and payment is likely to be exceedingly long. With such a delay, the resulting increased vendor cost for credit sales either would be passed on to the beneficiary, and ultimately the program, or it would be shifted to private patients. Control of payment and utilization would be difficult.

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[1] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968, pp. 172–174.

[2] Task Force on Prescription Drugs: "The Drug Makers and the Drug Distributors," U.S. Government Printing Office, Washington, D.C., 1968, p. 80.

Since the program administrator would not deal directly with vendors or drug makers, cost controls could not be effectively applied. If reimbursement were based upon "customary charges,"[a] program costs would rise steeply. If an indemnity price schedule[b] were established, inflationary increases would be absorbed by the recipients, and the intended economic relief would be lessened perhaps to the point of evaporation.

In addition, utilization review efforts[c]—both to encourage rational drug therapy[3] and control benefit abuse—would be far from satisfactory since patient reimbursement would (1) involve delays in the submission and recording of prescription information, and (2) provide a more limited data base than could be achieved under a vendor payment approach.

Vendor Reimbursement

An alternative to direct patient reimbursement is payment made to the pharmacist, physician, or other drug dispenser—an approach widely used in most public and private prescription drug programs today.[4] State drug programs, for example, show that direct vendor reimbursement is feasible and can provide accurate claims data.[5] It is probable that the number of prescriptions processed would be greater and benefit costs higher when the vendor is paid, since patients are more likely to have prescriptions filled when they do not have to pay the cost immediately themselves and then wait for reimbursement. But fewer unfilled prescriptions could result in better patient health and ultimately in lower total health care expenditures. Furthermore, some of the additional benefit cost would be offset in lower administrative expense resulting from more accurate claims data and automated claims processing.

Either Patient or Vendor Reimbursement

Benefit payment to either the patient or the vendor is not common in health insurance, although two current examples may be found in the Supplementary Medical Insurance Program for the elderly under Medicare and the CHAMPUS program[6] which covers military dependents. Certain advantages and disadvantages are associated with this approach.

Administration of a drug insurance program wherein either the vendor or patient may be reimbursed would offer maximum discretion to the participants. Such a policy, however, would also pose obvious difficulties: confusion on the part of vendors and patients, slow submission of claims by patients, an increase in incomplete or inaccurate claims, a probability that reimbursement controls would be diluted, high administrative expense due to duplicative systems required to process claims from two basic sources, and the like.

DETERMINATION OF REIMBURSEMENT

Regardless of whether payment is made to the beneficiary or the vendor, there are important choices to be made concerning the method of computing the amount that will be reimbursed. The question of direct cost-sharing is not at issue in this instance.[d] Rather, the question is one of establishing product allowance policy on the one hand and vendor dispensing allowance policy on the other.

A number of different reimbursement methods are currently in use in governmental and private drug programs.[7] None is without its disadvantages and none has been hitherto applied in the United States in a program which may be as large as the Medicare program now under consideration.

Evaluation of alternative methods of reimbursement should take into account a number of goals. For example, an ideal formula should—

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[a] See p. 29.

[b] See p. 17.

[c] See Chapter 8.

[3] Task Force on Prescription Drugs: "The Drug Prescribers," U.S. Government Printing Office, Washington, D.C., 1968, p. 3.

[4] "Current American and Foreign Programs," *op. cit., passim.*

[5] "Current American and Foreign Programs," *op. cit.*, pp. 120, 172.

[d] See Chapter 5.

[6] *Ibid.*, pp. 8–10.

[7] "Current American and Foreign Programs," *op. cit., passim.*

- reward manufacturers of drug products and dispensers of prescriptions according to their economic costs based upon an efficient use of resources and competitively determined price levels;
- neither encourage inflationary price increases nor shift part of the cost of drugs from beneficiaries to nonbeneficiaries;
- minimize the cost of drug therapy by providing incentives to drug producers and distributors to improve the efficiency of their operations;
- be simple enough to be understood by all program participants;
- promote the supply of drug products and vendor services of high quality; and
- involve reasonable administrative costs.

As noted above, there are two distinct cost elements associated with the dispensing of a prescription: (1) those expenses related to the manufacture and distribution of the drug product used in the prescription, and (2) overhead expenses, including provisions for profit, incurred by the vendor in dispensing the prescription.

Each of these two elements should be considered independently before the level of reimbursement is determined, since it is possible to adopt one policy for one element and a different policy for the other. Final establishment of a reimbursement policy requires ultimately that a method of compensation for product cost be selected for use in combination with a particular method for covering vendor dispensing expenses.

REIMBURSEMENT FOR PRODUCT COST

In highly oversimplified terms, the pricing system currently used by most drug manufacturers is based on a list price less discounts.[8] Each drug item has a catalog price, together with a series of discounts or reductions in this price available to the drug vendor. These discounts may differ between types of vendor; i.e., community pharmacies may receive discounts different from those available to hospitals, physicians, clinics and government facilities. A vendor may purchase a drug at one price if he buys directly from the manufacturer and at another price if he buys through the wholesaler.[a]

In addition to these price reductions, or trade discounts, quantity discounts are offered on large purchases of drugs. Moreover, some manufacturers grant cumulative quantity discounts based upon the quantities purchased throughout the year, or similar time period, with adjustments in drug prices at the end of the period. Furthermore, cash discounts may be offered.

The actual cost of the drug is therefore not readily ascertainable from invoice records at any one time, and, indeed, may not be known until the end of the year in which it was purchased.

In addition to manufacturers' catalog prices, two standard reference sources, the *Red Book* and the *Blue Book*, periodically publish drug price lists.[9] The price in these source books is usually the average listed wholesale price of the drug at the time of publication, and tends to be about 10 or 15 percent above the actual average acquisition cost.

In addition to price variations within a particular vendor establishment, prices vary among different types of outlets dispensing drugs. The acquisition cost of a product to nonprofit hospitals, for example, may be much less than the cost for the identical product to community pharmacies.[10] Thus the Veterans Administration estimates that it saved over $1 million between fiscal year 1964 and fiscal year 1966 by having prescriptions filled in VA pharmacies instead of local community pharmacies; a large portion of this saving resulted from the reduced acquisition cost of the drugs used (see Table 1). The cost of a particular drug product to a chain store may be less than that to a community pharmacy, but greater than the cost to a nonprofit hospital,[11] or to a dispensing physician or clinic.[b]

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[8] "The Drug Makers and the Drug Distributors," *op. cit.*, pp. 31–33.

[a] The manufacturer may grant additional discounts to drug wholesalers.

[9] "The Drug Prescribers," *op. cit.*, pp. 31, 49–50.

[10] "The Drug Makers and Drug Distributors," *op. cit.*, p. 73.

[11] *Ibid.*, p. 73.

[b] For example, a group of pharmacists recently sued a pharmaceutical manufacturer for violation of the Robinson-Patman Act, on the grounds that the manufacturer had offered a drug product to physicians and to clinics at a cost much lower than that to local pharmacists. (Unless the former purchased supplies in larger quantities than did community pharmacies, no economic basis for such a price distinction existed. In short, product pricing was being used as a promotion device and not to reflect the

Table 1

Comparative Prices of Selected Drug Products to Governmental and Private Purchasers[a]

Product	Date	Price to DSA[b]	Price to Community Pharmacies
Reserpine Ciba 1,000 tablets 0.25 mg	Nov. 1964	$6. 95	$39. 50
	May 1966	7. 15	39. 50
	Nov. 1966	3. 95	39. 50
	Dec. 1966	3. 95	39. 50
	Apr. 1967	3. 95	39. 50
		Price to VA[c d]	Price to Community Pharmacies
Reserpine Ciba 1,000 tablets 0.25 mg	1963	$1. 10	$39. 50
	1964	2. 20	39. 50
	1965	2. 20	39. 50
	1966	7. 19	39. 50
	1967	7. 19	39. 50
		Price to DSA	Price to Community Pharmacies
Penicillin G Potassium Squibb 100 tablets 250,000 units	July 15, 1966	$0. 707	$13. 68
	Dec. 6, 1966	0. 79	13. 68
	July 7, 1967	0. 668	13. 68
	Aug. 31, 1967	0. 75	13. 68

[a] Source: U.S. Senate, Select Committee on Small Business, Subcommittee on Monopoly: "Competitive Problems in the Drug Industry," U.S. Government Printing Office, Washington, D.C., 1967, Part 3, pp. 917, 1110.

[b] DSA—Defense Supply Agency, Department of Defense.

[c] VA—Veterans Administration.

[d] Price derived from price per 5,000 tablets.

In the discussion below, six different methods for determining product cost are considered in some detail. They include the following:

- Standard wholesale cost.
- Maximum allowable wholesale cost.
- Indemnity fee schedule.
- Actual acquisition cost.
- Negotiated price list.
- Direct reimbursement.

Standard Wholesale Cost

In the CHAMPUS program for military dependents, in some State plans and in some private programs, the standard wholesale cost of the drug is used as the basis of reimbursement for product cost. The standard wholesale cost is defined as the cost of the drug product as listed in a standard reference book, such as the *Red Book* or the *Blue Book*. As pointed out above, these reference book costs are generally higher than the actual cost paid by the typical community pharmacy; the difference between actual and book price may be even greater for nonprofit hospitals and for clinics owned by physicians. In most instances, therefore, the vendor is reimbursed by the drug program at a level which is higher than his actual acquisition cost.

The use of such a system in a drug insurance program inflates the cost of providing drug products for beneficiaries. Some plans attempt to make up for this by reducing the vendor payment for dispensing services to an amount below that of the actual cost. This is administratively possible when the payment for the drug product goes directly to the vendor. It avoids meeting the problem of determining actual acquisition cost and thus reduces administrative costs since no audits are needed to determine product cost. In addition, a standard cost can be built into an automated claims processing system, thus reducing the expense of that activity.

Such a reimbursement plan could encourage inflationary price increases by manufacturers since it would offer no incentives for manufacturers to keep prices constant or to reduce product costs. This problem would become more acute as larger segments of the prescription market are paid for out of government funds. In addition, such price increases would also be passed on to private customers. There would be no incentive for drug makers to improve their manufacturing efficiencies nor for drug vendors to improve their purchasing practices.

Maximum Allowable Wholesale Cost

One approach for controlling drug program outlays is the establishment of maximum allowable wholesale costs for multiple-source drugs. While products from single-source suppliers would be paid for on the basis of actual cost, or some variation of such cost, the program administrator would review the acquisition cost for each brand of a

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economic costs associated with dispensing to different vendors.) The pharmacists contended that they were in competition with these clinics, and that the manufacturer's practice was unfair. The suit was settled out-of-court, when the manufacturer stated it would change its policy and sell to both parties at the same price.

particular multiple-source drug used in the program and then establish a maximum price for that drug. In most cases, the maximum price would presumably be less than that of the highest-cost brand but more than that of the lowest-priced brand of the drug. A physician would be free to prescribe any drug product he desired, but the vendor would be reimbursed only for the maximum allowable amount. The patient, then, would be required to pay any difference between the reimbursement allowance and the actual cost.

Some advantage might accrue to recipients if pharmacists would dispense a chemically equivalent drug product when a brand-name drug was prescribed. (Physicians could retain the right to prevent such action if they feel this would be in the best medical interest of a particular patient.) State laws, however, generally prohibit a pharmacist from serving the needs of his patients in this manner.[12]

Under this reimbursement system, it has been assumed that patients would try to influence physicians to prescribe only those brand-name products which could be purchased at a price equal to or less than the allowable cost and thereby relieve themselves of additional expenses. It has similarly been assumed that generic-name prescribing could have the same effect if pharmacists and other drug vendors would use low-priced, quality products.[13] Unfortunately, this does not appear to be an effective means for providing very large economic relief to most beneficiary recipients. The lack of knowledge on the part of patients, and their hesitancy to discuss such matters with physicians, would preclude them from exercising much influence upon physician-prescribing habits, and consequently at least some patients would remain saddled with high drug costs under a program purporting to provide them with relief in meeting drug expenses.

Reimbursement on the basis of a maximum allowable cost might reduce the overall cost of a drug program. Some manufacturers whose drug product prices are above the allowable amount might even reduce their prices to the reimbursable level for the benefit of both public and private consumers. Administrative expenses would be lower under this approach, since vendor audits for acquisition cost concerning multiple-source products would not be necessary.

Savings resulting from the application of maximum allowable cost are likely, however, to be extremely limited. This system offers little or no savings for most drugs—about 80 percent of them—on the market, since these drugs may be purchased from only one source, have no chemical equivalents available, and thus can be obtained at only one price. Moreover, under this approach, all the problems of establishing the cost of single-source drugs still remain.

As noted above, in cases where multiple sources of drugs are available, some manufacturers might lower the prices of these products to meet the maximum limits. These same producers might at the same time, however, increase the price of the single-source drugs they produce in order to make up for lost revenue, thus negating the "savings" achieved under maximum allowable cost. Anticipated program economies would vanish under such a move. In addition, private patients would experience the same shift of cost from one drug to another, and little incentive for improved efficiency would be provided.

Indemnity Fee Schedule

An approach similar to the maximum allowable wholesale cost system is the indemnity fee schedule. As in the maximum allowable wholesale cost technique, the government could establish a maximum amount for drugs dispensed to beneficiaries, but in this case the reimbursable amount would be established for each drug product no matter whether it was produced by one or by many manufacturers. The program administrator would thus determine a "reasonable cost" indemnity allowance for each product on the market. In some cases, the indemnity allowance might be equal to the actual market price of the product; in others, it might be less than the actual price. The patient would be required to pay any difference between the actual price and the indemnity allowance.

Program expenditures could be held to a minimum under this method. By holding the indemnity fee schedule relatively constant, the government could avoid paying for inflationary increases in drug product prices. The burden of such price increases would, of course, be shifted to beneficiaries who could least afford them.

The advantage of this system over the maximum allowable cost system, in addition to providing program cost savings, lies in the fact that drug manufacturers could not increase the prices of their single-source drug products for beneficiaries at the same time that competitive pressures decreased the prices of their multiple-source products. However, since the consumers would pay any difference between allowable price and market price, this method offers inadequate incentives for the manufacturer to prevent inflationary drug product price increases.

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[12] "The Drug Makers and the Drug Distributors," *op cit.*, p. 80.

[13] Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, pp. 36–37.

The other limitations and advantages of the maximum allowable cost system also apply to the indemnity system. In addition, indemnity allowances could be reduced in order to counteract unpredicted increases in utilization, thus stabilizing program cost. But this characteristic is likely to pose a heavy burden for the beneficiary, especially if prescription prices should continue to rise.

Actual Acquisition Cost

Variability in acquisition costs as outlined above would make it difficult for the government, or an insurance carrier, to establish one uniform—yet equitable—product allowance policy. Either an established cost could be so low that it would fail to cover the actual cost for some retail outlets, or it could be so high that it would yield excessive profits to some vendors and consequently impair resource allocation and competition.

In order to cope with these and related problems, it has been proposed that programs should reimburse for drug products on the basis of the actual acquisition cost of the product to the vendor. Such a technique is currently employed by a number of State Medicaid programs.[14]

This approach has certain evident advantages, but it likewise poses obvious disadvantages. The administrator would be required to conduct continuous and costly field audits in order to determine the acquisition cost for each individual dispensing outlet. These expenses could be minimized if three audit functions—determination of product cost, determination of overhead expenses, and detection of fraud—were conducted as a combined and coordinated effort.

Many pharmacists, drug manufacturers and physicians appear to support this approach. It does not interfere with present marketing and pricing systems. There is no incentive to shift costs from public patients to private patients, since both pay their respective share of drug product costs. But because of the complexity of cumulative and other discounts, it is exceedingly difficult for the administrator, and even for the pharmacist, to determine the actual cost of the drug used in filling a prescription. Indeed, as noted above, it may take more than a year after the prescription is dispensed to determine the actual cost of the product.

Extensive, costly vendor audits would also be needed to prevent vendors from submitting fraudulent claims based upon drug product costs higher than actual acquisition costs. Program directors for Medicaid plans note the problems in auditing for acquisition cost. Many of them have informally indicated that a large segment of fraudulent drug claims results from an overstatement of acquisition costs by vendors, leading to increased program and auditing expenses. Such administrative expenses cannot be entirely avoided even though the vast majority of pharmacies report to the best of their ability the actual costs of drug products.

Administrative expenses might be reduced if an extensive study of the purchasing patterns of the various drug vendors were undertaken and used to establish prices by "vendor class." Since vendors of the same general characteristics (i.e., type of establishment, location, prescription volume, etc.) may be expected to purchase drug stocks generally in a similar manner and in similar quantities during a given period, their acquisition costs might also be expected to be similar. For example, it might be established that most community pharmacies in one category, dispensing 40 to 75 prescriptions a day, buy a certain drug in quantities of 1,000 tablets, while outlets in a different category typically buy it in larger amounts at a lower price per tablet.

If such characteristics could be identified, it would be possible to place each vendor in a particular class, and thereafter a continuing study of manufacturers' and wholesalers' drug prices would allow the program administrator to determine with considerable accuracy the actual acquisition cost of each drug product for each such class. Reimbursement for the product to all vendors within a class would then be the same predetermined amount, regardless of the amount actually paid. A drug vendor would be shifted from one class to a new category whenever his classification characteristics might change.

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[14] "Current American and Foreign Programs," *op. cit.*, pp. 34–90.

Under this system, detailed and expensive audits for vendor acquisition costs would not be necessary, and the program benefit and administrative costs could be held to a minimum. This approach would provide an incentive to the vendor to improve his inventory control program in order to bring his acquisition costs in line with similar outlets, but no incentives would be provided to manufacturers for more efficient operation, and there is nothing in this plan to prevent unnecessary drug price increases.

Negotiated Price List

The prescription drug programs in Australia [15] and New Zealand,[16] and more recently in Ontario, Canada,[17] use a different approach to reimbursement for product cost. In each case, the manufacturers' prices for major prescription drugs are negotiated by the government with the various drug makers, and "negotiated price lists" are subsequently distributed to physicians, pharmacists and hospitals. Physicians may consult the list to select a drug product of acceptable quality at a low price.

In the Canadian program, since the negotiated price is the price which all purchasers—government, private pharmacy, hospital and physician—must pay, the manufacturer may not raise prices to the private sector to make up for low government prices. Thus, an incentive is provided to manufacturers to negotiate a reasonable price for all products. As noted elsewhere,[a] [18] Canadian patent laws provide for compulsory licensing on all drug patents, and—at least in theory—price competition is thereby possible for all drug products. Quality standards for each generic drug are established by a committee of drug experts. No product is included in the negotiated price list if it does not meet minimum standards.

Direct Reimbursement

The Federal Government is the largest single buyer of drug products in the United States, purchasing drugs directly for use by the military, the Veterans Administration, the Public Health Service, the Department of State, and other agencies.[19] In addition, the government pays for drugs indirectly through such programs as Medicare, Medicaid, CHAMPUS, and the VA Hometown Services program.[20]

Direct Purchase. During fiscal year 1968, the Veterans Administration, the Department of Defense, the Public Health Service, and other agencies purchased drugs amounting to $184.6 million, or 5.2 percent of the dollar value of the output of the U.S. pharmaceutical industry (Table 2).[b] More than 80 percent of these purchases were made either by means of competitive bids or through negotiated contracts with individual suppliers, and without any sacrifice of drug quality.

The agencies now buy most of these products on a generic basis, and often with quality standards higher than those found in the official compendia. They conduct their own plant inspections and engage in extensive quality control studies. The recipients of such products are thus guaranteed the highest quality of drugs on the market, usually at the lowest possible cost to the government. In contrast, the public has no such guarantee on either generic or brand-name drugs, and generally must pay a higher price for the drugs they purchase.

The difference in prices paid for the same drugs by community pharmacies and by Federal agencies has been widely discussed. Some of these differences were presented in Table 1.

Indirect Payments. In addition to direct drug purchases, the Federal Government shares in the cost of drugs used by Title XVIII inpatient recipients, Title XIX recipients, Title III recipients, military dependents and others. In fiscal year 1968, these payments amounted to $297.6 million, or 8.6 percent of the pharmaceutical manufacturers' dollar output (Table 2). The Title XIX costs are shared by the State Governments, with the Federal Government providing at least 50 percent of the funds. The total portion of the pharmaceutical industry output obtained through these programs is therefore far higher than that reported here.

The Federal Government does not apply the same quality and cost controls to these programs as it now applies to its direct purchase operations.

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[15] *Ibid.*, p. 139.

[16] *Ibid.*, pp. 185–186.

[17] Ontario Department of Health, Toronto, Personal Communication, November 1968.

[a] See also p. 23.

[18] "Current American and Foreign Programs," *op. cit.*, p. 145.

[19] *Ibid.*, pp. 4, 15, 19.

[20] *Ibid.*, pp. 6, 8, 13, 20–22, 34 *et seq.*

[b] These fiscal year 1968 figures update fiscal year 1967 figures published elsewhere by the Task Force.

Table 2

Estimated Federal Expenditures for Prescription Drugs, Fiscal Year 1968 (In millions)[a]

	Product Cost	Overhead	Total
Direct Purchase:			
Department of Defense	[b] $125.7		
Public Health Service	[c] 4.5		
Veterans Administration	[d] 44.9		
Federal Supply Schedule Contracts	[e] 3.5		
PHS Communicable Disease Center	6.0		
Total Direct	$184.6		
Reimbursement Programs:			
CHAMPUS In-Hospital	$7.1	$7.1	$14.2
CHAMPUS Outpatient	0.3	0.3	0.6
VA Hometown Pharmacies	1.5	1.5	3.0
Public Health Service	0.5	0.5	1.0
Medicare In-Hospital	185.3	185.3	[f] 370.6
Medicaid Outpatient	65.7	65.7	[g] 131.4
Medicaid In-Hospital	36.7	36.7	[g] 73.4
OEO Vendor Programs	0.5	0.5	1.0
Total Reimbursement	$297.6	$297.6	$595.2
Total all Federal Drug Expenditures [h]	[i] $482.2	$297.6	$779.8
State Expenditures in Federally-Sponsored Programs	$92.6	$92.6	$185.2

The drugs used in these programs are not obtained through centralized and competitive purchasing systems; rather, the prevailing market price is paid for all drug products. The drugs are not generally purchased on a generic basis, as under the direct purchase programs, unless the State participating in the program adopts a generic purchase plan for recipients. Nor are the quality standards for drugs procured under the direct purchase programs applied to these indirect payments.[21]

The Federal Government thus applies two different sets of criteria to its drug programs—one, for beneficiaries under direct purchase programs, involving less expensive and probably higher quality drugs, and the other, for beneficiaries of indirect payment programs, involving more expensive drugs of possibly lower quality.

These indirect payments under government programs account for a higher expenditure of tax funds than do the direct purchases. With the anticipated increases in Title XIX participation, nearly 14 percent of the value of all prescription drugs produced in this country will be used in these programs by 1971. At that time, the total Federal drug purchases for existing programs are expected to take about 19 percent of the dollar output of the drug industry. If comprehensive drug cov-

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[a] Based on available data, February 1969. Source: Office of Research and Statistics, Social Security Administration.

[b] Includes $104.8 million purchased through Defense Supply Center, Philadelphia, Pa., approximately $16.5 million purchased through Federal Supply Schedule Contracts, and $4.4 million purchased through other sources.

[c] Includes $1.0 million purchased through PHS Supply Service Center, Perry Point, Md., and $3.5 million from other sources including the Veterans Administration.

[d] Includes $22.1 million purchased through Federal Supply Schedule Contracts administered by VA for General Services Administration; remainder purchased through other sources.

[e] Includes purchases for miscellaneous Federal agencies.

[f] Includes only drugs provided under inpatient hospital and extended-care facilities provisions of Part A. Does not include drug cost to the patient represented by the deductible and co-payment features of the program; excludes payment made for drugs administered in physician offices and through outpatient diagnostic services.

[g] Includes other Federally-supported State public assistance programs.

[h] Does not include the reimbursements of over $55.0 million annually for both inpatient and outpatient drugs under the Federal Employee Health Benefit Care Act, of which the Federal share, based upon premium contributions, is $17 million annually. It should be recognized that because of the deductible features of most programs, these figures do not accurately reflect total drug consumption by the insured. Actual expenditures for drugs by persons enrolled under these programs are conservatively estimated to be well over $100 million annually.

ESTIMATED 1967 FEDERAL EMPLOYEE DRUG EXPENDITURES AND BENEFITS

[In millions]

	Inpatient	Out-patient	Total
Expenditures	$39.0	$75.0	$114.0
Benefits	37.0	18.0	55.0
Ratio of Expenditures to Benefits	95%	24%	48%

[i] Represents 13.8 percent of total U.S. pharmaceutical industry sales volume (5.2 percent for direct purchase and 8.6 percent for indirect reimbursement).

[21] "The Drug Prescribers," *op. cit.*, pp. 33–34.

erage is added as a benefit to Medicare recipients, the total Federal payments—direct and indirect—would account for about 44 percent of the industry sales (Table 3).[a]

Table 3

Estimated Federal Drug Purchases, Fiscal Year 1971, With Comprehensive Medicare Drug Program, as Percentage of Pharmaceutical Industry Output

	Percent of Pharmaceutical Industry Sales Volume
Direct Government Purchases (Dept. of Defense, VA, PHS, OEO, etc.)	4. 8
Title XVIII (Inpatient and outpatient)	29. 9
Title XIX	8. 2
CHAMPUS and others	0. 8
Total	43. 7

The responsibility of the government to both the public and the industry under these conditions is evident. According to a U.S. Senate report, the government should "seek the goal of drug supplies of the highest quality, safety, and efficacy at the best prices obtainable by Federal quantity purchasing."[22] Prices paid for drugs must be fair both to the industry and to the taxpayer by providing for a fair profit to the drug makers without incentives for inflationary price increases to the public. If the allowances under government programs are too low, additional economic burdens would be shifted to those nonbeneficiaries needing medication; if they are too high, needlessly large profits would accrue to drug producers.

The Federal Government has been urged to adopt procedures providing acceptable drug quality standards for all its purchases—direct or indirect.

> "Interagency uniformity for uniformity's sake is not sought by anyone. But neither should needless discrepancies be tolerated if savings can be achieved by better and more uniform actions. The Federal Government should achieve the greatest possible yield from every dollar of drug purchases. It should achieve every possible saving from quantity purchasing of drugs of the highest safety and efficacy."[23]

For some products, as in the case of the unusual overseas requirements of the Department of Defense and the Department of State, it is evident that special quality standards are required. Within the United States, however, it seems appropriate that standards should be the same for all products paid for by the Federal Government, and the same drug acquisition and quality control practices currently utilized by some Federal agencies could well be applied to a Medicare drug insurance program and any similar program involving Federal participation. This would obviously pose many questions of public policy, and offer a variety of approaches.

Under one approach, for example, reimbursement could be made directly to the drug manufacturer for those products used by the pharmacist in dispensing prescriptions for beneficiaries of Medicare, Medicaid, CHAMPUS and similar Federal programs. The vendor could still be reimbursed for the service he renders in dispensing the prescriptions under one of several alternative procedures. In addition, it would be necessary for the government to finance (1) product purchase and (2) product distribution.

Perhaps the most efficient arrangement would have responsibility for purchase of drug products for all Federal agencies assigned to a single Federal Government Drug Procurement Office. This office would thus carry the responsibility of fulfilling the recommendations of the U.S. Senate report on *Interagency Drug Coordination* to assure efficient, economical procurement of high quality, safe and efficacious drugs for all agencies.[24] Since the Department of Health, Education, and Welfare would be the major purchaser of drugs within the Federal Government if direct purchase were used for Medicare and Medicaid, as well as for the Public Health Service, the procurement office might be located in that Department, but utilizing the necessary expert knowledge and competency already demonstrated by the Defense Personnel Support Center of the Department of Defense, as well as by the procurement branches of the Veterans Administration and the Public Health Service.

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[a] By 1975, when all Title XIX and all other government programs are fully operative, the Federal purchases could total 46.3 percent of industry output.

[22] U.S. Senate, Committee on Government Operations, Subcommittee on Reorganization and International Organizations: "Interagency Drug Coordination," U.S. Government Printing Office, Washington, D.C., 1966, p. 4.

[23] *Ibid.*, p. 141.

[24] *Ibid.*, p. 4.

While the total volume of drug purchases would be much larger than the total for all these agencies now, very few additional staff personnel would be necessary, since the number of needed personnel is a function of the number of drug products purchased and not the dollar volume of purchases. Centralized purchasing for all drug products would thus result in more efficient use of existing government employees by minimizing existing duplicative functions.

Procurement Procedures. In order to achieve maximum economies afforded by this procedure, virtually all drug products used by government programs—both those provided directly and those provided as insurance benefits—would be purchased directly. Individual agency drug specifications and quantity needs would be forwarded to the procurement office, which would then establish individual drug specifications best meeting the needs for all agencies. When necessary, separate specifications would be established to meet unusual requirements of the Department of Defense and the Department of State.

All drug specifications would be established and published by the office, and competitive bids would be solicited from drug producers meeting its standards. Where only one producer was in operation because of an existing patent, the competitive bid would be replaced by contract negotiations or—if necessary—purchase of the patent or a suitable license. Contracts for a nonpatented generic drug could be awarded to more than one bidder.

Good Manufacturing Practices, developed in conjunction with the Food and Drug Administration,[25] would also be published, and both pre- and post-award plant inspections—similar to those now required by the Department of Defense [26]—would be carried out by FDA at the request of the procurement office. The drug manufacturers would thus be spared the duplicative inspections they now face from FDA, the Department of Defense, the Veterans Administration and the Public Health Service. These inspections would meet the requirements of the plant inspections now required of FDA by the 1962 Kefauver-Harris Amendments. Additional plant inspectors would be needed by FDA, but these could be drawn from staffs of existing agencies now engaged in this function.

No contract would be awarded to a company before its facilities had been certified through inspection. Failure to pass a post-award plant inspection would be cause for revocation of a contract. Failure to receive a plant certification at one inspection, however, would not prejudice the company from making bids at a later date if manufacturing practices had been satisfactorily upgraded, but repeated failures of post-award inspection could be cause to prohibit any future contracts. The cost of such inspections could be borne by the drug manufacturers through a licensing fee.

The problems of intrastate manufacturers would no longer exist, since neither the name or location of the firm nor the brand name of its product would influence selection. Only the quality of a product and its price would be involved in the purchase decision.

Installations patterned after the PHS's Perry Point Supply Service Center [27] could be established at several points throughout the country in conjunction with existing Federal drug supply depots. These centers would provide special repackaging, labeling and compounding needs for the various Federal agencies. In addition, and in cooperation with other agencies, they would conduct continuing quality control tests on all drugs purchased in order to ensure that standards were maintained.

An extensive analysis of drug product inventory requirements would have to be undertaken well in advance of the beginning of a government purchase plan. Quantities of drugs needed, as well as costs and distribution locations, would have to be studied carefully in order to plan timely acquisitions of the products expected to be used.

Patent Policy and Industry Competition. The maximum benefits of centralized and competitive purchasing for drugs can be achieved only if there is strong competition within the pharmaceutical industry.[28] In the current market situation, effective competition exists only for about 20 percent of drugs produced in the United States. In nearly all other cases, the existence of a patent results in the production of a drug by a single manufacturer, and bids are totally meaningless.[29]

Unlike private drug outlets, Federal purchasing agencies have four alternatives open to them. *First* they can and do enter into price negotiations with the manufacturers of single-source drugs.[30] *Second*, if agreement on a reasonable price cannot be reached during the negotiation, the agencies can purchase the drug from those foreign countries where drug patents are not recognized.[31] With the present balance of payments problem, this policy is not feasible for a Medicare program. Nor would the purchasing of drugs in foreign countries be a suitable alternative in all cases, since foreign producers may not be able to manufacture adequate supplies to cover the needs of all U.S. Government programs. *Third*, the agencies may contract with unlicensed producers—domestic or foreign—to manufacture the drug and settle any resulting patent litigation in the courts.[32] Under these conditions, no injunctions against further patent violations would be available to the patentee, and the government could continue to buy from other producers while paying royalties to the patent holder.

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[25] Brodsky, Philip: "Drug Plant Inspections," FDA Papers 1 (No. 4): 7 (May 1967).

[26] "Current American and Foreign Programs," *op. cit.*, pp. 3–5.

[27] *Ibid.*, pp. 15–16.

[28] "The Drug Makers and the Drug Distributors," *op. cit.*, pp. 37–44.

[29] "The Drug Users," *op. cit.*, p. 36.

All these alternatives would be available to the government under the plan presented here. It is possible, however, that the administrator might be required to spend considerable time in patent litigation if they should be used. Accordingly, a *fourth* alternative, similar to the program under development by the National Aeronautics and Space Administration to eliminate the basis for patent suits,[33] is available and deserves consideration. In those cases in which there is only one producer for a needed product, the procurement office would try to induce the patentee to sell his patent rights to the agency. This would leave the office free to license, at a fee, any qualified producer who submits a reasonable bid for manufacturing the product. An alternative to such outright purchase of the patent would be to purchase a license from the patentee and then allow any producer who is awarded the contract the right to use it.

A proposed amendment to the Canadian patent laws is currently under discussion. It would allow the Commissioner of Patents to grant licenses for patents on drugs.[34] Under this amendment, the Commissioner would fix the amount of royalty or other payment to be made to the patentee, considering (1) the public welfare in terms of the lowest possible cost of drugs, and (2) due reward for research. The proposed amendment is intended to bring about compulsory licensing for drug products and manufacturing processes, with protection to prevent unduly high licensing fees. Other foreign countries have similar laws.[35]

Under this procedure, the manufacturer would presumably be compensated for all expenses involved in developing the patent for the drug product, plus a profit, thus stimulating productive research. Patents for most duplicative or combination drugs [36] would presumably not be purchased by the government. Since the government could license any number of manufacturers to produce a drug, competition would be stimulated at the manufacturer's level. These drug makers would be able to use their licenses to produce drugs which would also be dispensed in filling prescriptions for the general public, presumably resulting in lower retail prices for prescriptions without loss of quality.

Drug Product Distribution. Under the approach considered here, existing marketing channels, including private wholesale companies,[37] could serve effectively as distributors of Federally-purchased drugs for Medicare, Medicaid, and similar vendor service programs. Drug products used directly by the Department of Defense, the Veterans Administation, the Public Health Service and other Federal agencies would continue to be shipped by the producers to Federal supply depots or other Federal installations. The individual Federal installations would continue to purchase from wholesale units to satisfy emergency and unusual drug needs but these purchases could be made at the bid or negotiated price instead of at the current market price.

In remote areas where there are no Federal installations, regular wholesale market channels might be used to distribute all government-purchased drugs. In general, provisions could be made to use the least costly channel meeting government needs in all areas.

Purchases of drugs for Medicare, Medicaid, CHAMPUS and other programs in which the Federal Government shares in the financing would be accomplished by means of a paper transaction. Under an automated data processing system, for example, the pharmacist or other vendor dispensing a prescription to an eligible recipient would enter a claim to the program administrator through the system. The name, strength, dosage form, producer and quantity of the drug dispensed could be automatically transmitted at the same time to a supplier designated by the vendor. Each vendor would be free to designate any wholesaler or drug producer meeting government specifications as the supplier for each drug product used in a government program. When the vendor submitted a purchase request to his supplier, he would be billed only for that amount of the drug *not* dispensed to government program recipients.

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[30] "Current American and Foreign Programs," *op. cit.*, pp. 4, 15, 19–20.

[31] *Ibid.*, p. 198.

[32] "The Drug Makers and the Drug Distributors," *op. cit.*, p. 41.

[33] U.S. Senate, Select Committee on Small Business, Subcommittee on Monopoly: "Competitive Problems in the Drug Industry," U.S. Government Printing Office, Washington, D.C., 1967, Part 1, pp. 133–135.

[34] The House of Commons of Canada, Bill C–102, 1st Session, 28th Parliament, 17 Elizabeth II, 1968.

[35] "Current American and Foreign Programs," *op. cit.*, pp. 137 *et seq.*

[36] "The Drug Makers and the Drug Distributors," *op. cit.*, pp. 20–22.

[37] *Ibid.*, pp. 56–60.

If the drug were supplied through a wholesaler, the latter would pay the manufacturer only for that amount of drug *not* dispensed to program beneficiaries, and the government would be billed for the remaining amount by the manufacturer. The same billing procedure would apply to purchases made by retail drug vendors who buy directly from the manufacturer instead of through the wholesaler.

Wholesalers would be paid a wholesaling fee for all Federally-purchased drugs passing through their firms. The fee could be (1) a flat yearly amount to provide for wholesaling overhead costs and a profit, or (2) a percentage amount based on the volume of drugs distributed. The former system would provide greater incentive for more efficient wholesaling practices. Extensive study of wholesaling costs would be necessary in order to determine the proper fee.

Chain drugstores, hospitals and other large drug dispensers having warehouse facilities could also be defined as wholesalers and receive the proper wholesaling fee.

To meet the requirements of a government purchase program, the data systems network for Medicare [a] would need to provide for the use of the system for inventory control purposes, as well as for data transmittal and processing. Inventory control programs, including programmed purchase systems, would have to be developed for wholesale outlets. Such systems are now in use in many drug producer, drug wholesale and chain drugstore warehouse outlets. They need only be modified to include the necessary records to determine that portion of each order from a vendor to be paid by the vendor and that to be paid by the government.

Cost of Administration. Consolidation of existing drug procurement personnel from the Defense Supply Agency, the Veterans Administration, and the Public Health Service into one procurement office would introduce new efficiencies and reduce overlapping activities.

Few additional personnel would be required by the new procurement office. Little additional manpower would be needed for the development of drug specifications, and for the solicitation of bids and the granting of contracts. If all drugs were purchased centrally, it would be possible to reduce the total number of personnel now used. New personnel would be needed to study the flow of drugs, to make periodic inventory adjustments in drug vendor and wholesale outlets which result from changes in prescribing habits, and to audit manufacturers' and wholesalers' distribution data.

Additional personnel would be required to staff the centers in which the quality control test and the special repackaging, labeling and compounding procedures for Federal agencies would be conducted. The three Federal agencies, however, already have staffs for some quality control tests and for some compounding. Thus, only a relatively small increase in staff would be added for these purposes.

If the government should act as the purchaser of drugs, the problems of accurately determining the actual acquisition cost of drugs dispensed to recipients would be largely dissipated, resulting in lower administrative costs. Administrative expenses could be further reduced since the need for prompt vendor reimbursement would be reduced. Replacement of products, together with use of co-payment, would require only a relatively small payment to the vendor by the administrator, and vendors could more easily accept less frequent reimbursement. Such savings could more than offset any additional costs of the procurement office.

Program Expense for Product. Two different effects upon drug costs to the government can be anticipated under a government purchase approach for Medicare.

On the one hand, bids submitted by pharmaceutical manufacturers might be higher than current bids to Federal agencies. Some manufacturers use incremental pricing when submitting bids, pricing the product below the average unit cost and recovering little more than direct production costs. (It should be noted that the Federal Government pays indirectly for these lower bid prices when it pays the regular cost of drug products dispensed through Medicare, Medicaid, etc.) It is estimated that bid prices for direct Federal drug purchases under this system could increase by about 50 percent, or some $90 million per year, if manufacturers actually do use incremental pricing now for all Federal Government sales.

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[a] See pp. 42–43.

It is more likely, however, that most manufacturers currently recover all direct and indirect costs, including provisions for profit, when selling drug products to the government. The estimated increase of about $90 million in price, therefore, may actually prove to be closer to $20 million. This amount should be offset against the gross savings resulting from direct purchase. Taking this factor into account, it is estimated that net savings to the government as a result of direct purchase of drugs for a comprehensive drug program under Medicare might be in the neighborhood of $150 million annually.

In addition to the savings realized by the government, competition at the manufacturers' level could bring savings in drug costs to the public. Competition could be restored to the market through the purchase of patents by the government and the issuance of licenses to qualified producers. Profits of some pharmaceutical manufacturers would unquestionably fall, but their risks would also be less.[a] The manufacturer whose patented discovery has a significant medical value could expect to sell his patent to the government, recovering all development costs plus a research profit or a royalty of similar worth. Since proof of clinical efficacy would be required where necessary before a bid would be accepted, the question of therapeutic equivalency between brand and generic products would no longer be relevant.[38] The manufacturer would still be free to promote his brand-name product to physicians for use by the general public. Because of the advent of new competitors, each with a product acceptable for use under government programs, monopoly profits resulting from brand-name promotion could be expected to fall.

In addition, increased competition among manufacturers makes it unlikely that drug makers would increase prices to the public to make up for lower prices to the government. The private sector cost would tend to equal the public sector cost, except that the large quantity discounts would not be applicable to the private sector. Consequently, drug prices in the private sector might be slightly greater than the government price but considerably less than drug prices under current marketing practices.

Drug producers might attempt to shift costs radically from the public to the private sector, in which case the provision of prescription drug insurance for all age groups using a government-purchase plan could be considered.

REIMBURSEMENT FOR DISPENSING COSTS

In addition to payment for product cost, a prescription drug insurance program must provide appropriate payment for the services of a pharmacist.

Most pharmacists traditionally follow general retail practices in pricing prescriptions, and add a percentage markup or margin, based upon the selling price, to the cost of the drug product to determine the final price.[39] The difference between the acquisition cost of all drug products dispensed and the aggregate prescription prices received must be large enough to cover overhead expenses as well as to provide for a profit. Most vendors have a minimum prescription price, and if the calculated price is less than the minimum, the vendor charges the patient the full minimum amount. This practice results from a recognition that very low cost items are dispensed at a high loss when a percentage markup is used. These losses are balanced by the profit made on high cost products.

A growing number of pharmacists, believing that their services bear no necessary relationship to the cost of the drug product, charge a flat dispensing fee for each prescription regardless of the cost of the product.[40] The fee is set at a level sufficient to cover all costs incurred in dispensing the prescription plus a profit. Since the actual service performed by the pharmacist does not vary greatly from one prescription to another, the same fee can be applied to all prescriptions.[a]

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[38] "The Drug Prescribers," *op. cit.*, pp. 34–36.

[a] Manufacturing volume for innovative, efficient pharmaceutical producers would rise and profits would accordingly increase. Firms not able to compete on this basis would face a decline in profits.

[39] "The Drug Makers and the Drug Distributors," *op. cit.*, p. 63.

These and other approaches that can be used in reimbursing for pharmacy services under a prescription drug insurance program deserve consideration. If one of these formulas is selected, policy decisions would be needed on whether reimbursement will be at the vendor's "usual and customary" amount, at a "reasonable amount," or at the economic cost of pharmacy services.

To provide the complete program formula, any one of these alternatives may be used with any one of the six product reimbursement alternatives discussed above. Any one may be used for an indemnity insurance program in which the beneficiary pays any difference between the established vendor dispensing fee and the charge actually set by the vendor for his services. Each is also compatible with any program in which the vendor agrees to accept the established amount plus the patient co-payment, if any, as full reimbursement.

Percentage Markup

A drug program could base the dispensing fee on a percentage markup which drug vendors would apply to the acquisition cost in order to determine the total prescription price. The established percentage would have to cover all economic costs required to dispense a prescription. Careful analysis of drug vendor operating costs will probably indicate that more than one percentage figure would have to be adopted. For example, the operating expenses of outpatient pharmacies in hospitals appear to be less than the expenses incurred by community pharmacies, and nonprofit hospitals and other nonprofit institutions would presumably not receive a sum to represent profit. Although State boundaries do not appear to be a factor in vendor costs, differences in costs between broad geographic areas would also have to be considered. Under this approach, drug vendors could be classified into appropriate categories, with percentage rates established for each category.

If there are variations in operating costs among outlets within such a category, the established percentage amount should probably be somewhat below the highest operating cost in order to provide incentives to marginal operators to increase their efficiency. On the other hand, setting the percentage too low would drive some outlets out of the programs and perhaps make pharmacy services less than adequate to beneficiaries.

Under this system of reimbursement, drug vendors would be able to shift costs from program beneficiaries to private sector patients. Experience in some State Medicaid programs, however, indicates that the established rate tends to become the prevailing rate in the community for both program and private patients. If the rate is established at an appropriate level, vendors under a Medicare program might be expected to follow the same course. Apparently, competitive forces within the community induce most vendors to seek the same price level for all patients.

The percentage-markup system appears to be a relatively easy system to administer. Once the rates have been fixed, the program administrator need only verify acquisition cost and eligibility of recipient before paying a claim. The system readily lends itself to automated data processing and low administrative cost.

The American Pharmaceutical Association and other professional groups oppose the use of the fixed percentage system.[41] The Government Accounting Office has stated its opposition to the use of a percentage markup for Medicaid programs, indicating that this system encourages the use of high-cost drug products when lower cost products are available.[42] If a prescription is written for a multiple-source drug, for example, the pharmacy makes a higher profit if a drug with high acquisition cost is used instead of a low-cost product, and program costs are thereby inflated.

In addition, an unscrupulous drug vendor could use a low-cost drug product and submit a claim for a more costly product, increasing profit even further. Auditing procedures would be necessary to establish and verify acquisition cost in order to prevent this type of overcharging for pharmacy service.

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[40] *Ibid.*, pp. 63, 66, 67.

[a] Some pharmacists charge a higher fee when the prescription is compounded in the pharmacy, since more professional time is required. In most cases, however, since very few prescriptions are compounded, this additional time can be ignored in determining the price to the patient.

[41] "The Drug Makers and the Drug Distributors," *op. cit.*, p. 63.

[42] U.S. Comptroller General: "Report to the Congress of the United States. Review of Pricing Methods Used by Various States in the Purchase of Prescribed Drugs Under Federally Aided Public Assistance Programs," U.S. General Accounting Office, Washington, D.C., 1967, p. 6.

The markup approach would become difficult to establish and administer if the government should become the purchaser of drug products, since the acquisition cost would probably be unknown to the vendor. Higher percentage rates would be required in order to provide sufficient income to cover vendor expenses when low-cost products were used. Under a percentage markup system, a sudden reduction in the acquisition cost of drugs would result in loss of income to the vendor for payment of overhead expenses. A similar increase in acquisition cost would raise the program contribution to pharmacy overhead and profit.

Flat Dispensing Fee

An alternative reimbursement approach would provide for a flat dispensing fee. As under the percentage markup system, the program administrator would set the fee based upon the costs incurred in dispensing the prescription. Program costs would be more easily determined than under a system using the percentage markup, since overhead expenses to cover dispensing would be calculated independently of product cost. Also, a known amount per prescription would allow the administrator to ascertain more accurately the necessary income for each pharmacy, since presumably there would be a series of fees that would be applicable to the various categories of vendors and that would equitably reflect variations in the cost of operation.

If the fee for a category or class of vendors were set at or below the average for the class, many pharmacies would be unable to recover all costs, and hence might refuse to participate or tend to subvert the program. On the other hand, if the rates were set at the 80th or 90th percentile, for instance, highly efficient vendors would be rewarded by extra profits equal to the difference between actual costs and the reimbursement fee. Further study and experimentation and consultation with the industry might indicate a reasonable middle position.

The use of the dispensing fee would be acceptable to many drug vendors. A recent study reports that 75 percent of chain drugstore executives favor the use of a dispensing fee for government programs.[a] Chain stores feel there is a need for a single fee for all their outlets within a particular geographic area, but this does not present any major obstacle to the use of a fee system. The system meets with the approval of the Government Accounting Office, the American Pharmaceutical Association and other professional organizations, but the National Association of Retail Druggists has opposed the use of government-established fee schedules.[b]

The use of a dispensing fee would not present any special problem for vendors so long as the program does not prohibit a vendor from charging government-program participants more than its regular clients. If a vendor normally uses a percentage markup, drugs with a low acquisition cost could thus be dispensed to private patients for less than the government allowance, while high-cost drugs would be dispensed to private patients at a price greater than the government would pay. If the vendor were required to charge the government an amount equivalent to the lower percentage markup amount for low-cost items, with no possibility of making up the losses on higher cost medications, the program would penalize the vendor inequitably.

The dispensing fee method has been criticized in that it inherently results in higher expenses for those who frequently purchase low-priced prescriptions. It is equally inherent in this method, however, that the flat fee results in reduced drug expenses for those who frequently purchase high-priced prescriptions. For the typical purchaser, or for a comprehensive drug program, the application of a flat fee is neutral—that is, it provides an average overhead charge, rather than one which is either subsidized or inflated.

The use of a flat dispensing fee lends itself to automated claims processing and low administrative costs. Since there is no incentive for a pharmacist to dispense high-cost brand-name equivalents when generic products could be used, it tends to result in lower program costs.

Some pharmacies have already adopted the fee concept in pricing prescriptions, and their number is apparently growing. Many more pharmacists would probably use the system if they could be certain that they would not suffer competitively. If the fee system were to be used as the method of reimbursing vendors for a drug program, these fears would be greatly lessened. Each vendor who participates in the program would know that all other vendors would follow the same system, at least for part of their activities.

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[a] Based upon data supplied by the National Association of Chain Drugstores, Inc., Washington, D.C., June 14, 1968.

[b] See p. 29.

Flat Dispensing Fee Plus Percentage Markup

This system combines the features—notably the disadvantages—of both the percentage markup and the dispensing fee systems. It has been used by some States in Title XIX drug programs, and by many drug vendors. In the State programs, the administrators have been forced to establish both the fee and the percentage amounts, thereby increasing administrative costs and complexities. There are no significant advantages to its use over either of the systems discussed above.

Bid Pharmacies

Unlike the systems in which rates for drug services are set by the government, the bid system would allow the vendor to establish his own fee. The program administrator would solicit bids on dispensing fees from interested vendors, and accept all bids which he feels are consistent with the necessary, economic cost of doing business. The dispensing fees may vary within an area, with each participating vendor being paid his respective bid amount for each prescription filled.

Built into the system is an incentive for vendor efficiency. Any bids which are considered excessive would be rejected. Such high bids would generally result from vendor inefficiencies or an attempt to obtain monopoly profits. New bids would be solicited frequently, perhaps every six or twelve months, to reflect changes in economic conditions and competitive situations.

Vendor audits would not be necessary to determine overhead costs, while accurate claim data could be expected. Continuing investigation of vendor operating costs would be necessary in order to provide the administrator with data to be used in evaluating bids.

The administrator would have to exercise care to see that sufficient pharmacies in convenient locations would be available for use by the recipients. It is possible that not enough vendors would submit bids, or low enough bids, to provide the necessary number of drug outlets.

Under this system, the vendor could shift costs to private patients. Competitive forces, however, would tend to limit such a shift, since prescription prices in noncontract outlets for private patients might be less. This system might also tend to create monopolies in the retail prescription market.

Overhead Expenses: General Considerations

In establishing a reimbursement formula for any system other than "usual and customary" charges or arbitrary indemnity, the program administrator would be faced with the problem of deciding which operating expenses are pertinent to dispensing the covered drug products. Certain expenses incurred by many vendors might not be considered as necessary to provide pharmacy services to beneficiaries, and excluding them from reimbursement computation would reduce program costs. Presumably such expenses as salaries, rents, utilities, legal and accounting fees, necessary licenses for the dispensing of drug products, taxes, interest, depreciation and provisions for profit would be included in the reimbursement calculations, but decisions on other questions would need to be made at the outset of the program.

Advertising Expenses. A decision by the program administrator to include advertising cost—unless this were banned by State or other laws—as a reimbursable expense may encourage more use of advertising by vendors. In this connection, it may be noted that institutional advertising could inflate costs, while price advertising could stimulate competition and reduce costs.

Trading Stamps. Since the purpose of a drug program for the elderly is to provide needed medications to recipients at reasonable cost, the use of trading stamps and similar promotions such as games and contests does not seem to be necessary. Reimbursing for them would needlessly inflate program costs.

Bad Debt Expense. Not all drug vendors offer credit to their clients, so that bad debt expense is not a universal problem. (According to the *Lilly Digest*, the average prescription pharmacy offering credit incurs a bad debt expense of 0.2 percent of the annual sales volume.)[43] If the payment for dispensed drugs, with the exception of deductible or co-payment amounts, were the responsibility of the government, it is difficult to consider bad debt expense as a reimbursable expense, since the debts would not be incurred through the program.

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[43] Lilly, Eli, and Co.: "Lilly Digest," Indianapolis, Indiana, 1966, p. 22.

Delivery Expense. As with credit, many vendors, provide delivery services for prescription drugs. Such services may be vital for infirm elderly patients who cannot otherwise get needed medications. On the other hand, it may sometimes not be in the patient's best interest to receive medications through a delivery service. Careful study of delivery services and the needs of the patients must be carried out before a policy to discourage or encourage their use is adopted.

Other Vendors. Other vendors such as nonprofit hospitals dispensing outpatient prescriptions would presumably not be paid a profit, but would be allowed a return consonant with the cost of maintaining capital. Proprietary hospitals, like community pharmacies, would be reimbursed at a rate which allows them a reasonable profit.

The problem of dispensing physicians is more complex,[44] and little is known about their operating costs. Physicians are in business to practice medicine, and they profit from their medical activities. Accordingly, it may be held that they should not profit from a pharmacy practice, particularly when they control the purchasing of drugs by their patients.[a]

Over-the-Counter Drugs. Physicians sometimes prescribe over-the-counter drugs alone or in conjunction with certain legend medications. If such OTC products were covered under a drug insurance program, several alternative reimbursement systems could be applied. For example, some State Medicaid programs reimburse for OTC's at the regular market price. Other States pay either the market price or a price based on a special OTC formula, whichever is lower, relying upon competition in the private sector to keep program costs at a minimum.

Reimbursement may also be made at the market price plus a billing fee in order to cover all costs and not provide incentives to shift program costs to private patients. (As has been stated above, expansion of government drug programs may result in less competition in the private sector, making this approach less reliable as a cost-controlling mechanism.) Finally, reimbursement may be made on the basis of the formula adopted for prescription drugs. Further study on the need for OTC drugs and on reimbursement systems for them is needed.

REIMBURSEMENT ACCORDING TO REASONABLE CHARGES

Under the present Medicare program, payments to physicians are made on the basis of usual, customary or reasonable charges. A similar method could be used for a drug program.

The drug vendor could be paid his usual price for each prescription unless the amount exceeds limits set on the basis of what is "usual and customary" in the community. The National Association of Retail Druggists has consistently and strongly supported this plan:

> ". . . the usual and customary charge concept is consistent with the hallmark of competitive forces under which retail pharmacy has thrived in the United States." [45]

Efficient pharmacists might be encouraged to become more efficient since—given a particular market price—this would increase their profits, but these reduced costs would not necessarily be passed on to the program. In addition, inefficient firms would not necessarily be encouraged to become more efficient. The system would perpetuate current operating practices of drug vendors.

In order to hold inflationary price increases to a minimum, the program administrator would need to develop profiles on pharmacies, physicians, and patients, and to cut off payments which are above a "reasonable" level.

The use of "usual and customary" price in a community as the basis for payment in a drug program would present administrative problems which are not common to other health insurance plans. For example, some pharmacies frequently charge different prices for the same quantity of a drug product, making it difficult for the administrator to set the "usual and customary" price.[46] In addition, as many as 50 or 60 separate prices would have to be established for each drug product to allow for the wide variation in the quantities prescribed. The initial determination of these prices could not be carried out before the implementation of the program.

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[44] "The Drug Makers and the Drug Distributors," *op. cit.*, p. 75.

[a] See also p. 48.

[45] Simmons, Willard B.; Letter to Social and Rehabilitation Service, Department of Health, Education, and Welfare, Washington, D.C., August 29, 1968.

[46] "Generic Prescriptions Not Lowest Cost, Study Finds." AMA News 10:1 (May 29, 1967).

Reimbursement according to "reasonable charges" in a drug insurance program would be inconsistent with a deductible plan making payments directly to patients. With the fluctuations that occur in the acquisition cost of drug products, and the time lapse between incurring the expense and submitting the claim, it appears to be impossible to determine the "reasonableness" of each prescription price. It would, therefore, be impossible to decide whether the deductible amount had been met and the patient had qualified for program benefits.

CENTRAL (GOVERNMENT-OWNED) PHARMACIES

A prescription drug insurance program could be administered through the use of centralized pharmacies owned by the Federal Government. This approach would be more compatible with a program limited to coverage of maintenance drugs, under which mail-order services could be widely provided, than with a comprehensive drug program.

Since the pharmacies would operate as nonprofit firms, dispensing costs could be lower than those of profit-making outlets. Efficient use of pharmacists and, where appropriate, pharmacist aids could also contribute to low program costs. Other advantages would include improved availability of accurate claim data, the lack of incentives for fraudulent claims, and low administrative expenses.

The use of such a health care delivery system, however, would represent a drastic departure from existing public policy, since it would be contrary to the principles of a free-enterprise system. Government-owned pharmacies would be expensive to establish, and it may be difficult to recruit adequate professional staffs. No incentives would exist for efficient operation. Critical shortages of pharmacists in the private sector could result, and drug prices to private patients could be increased to make up for the loss of income to existing pharmacies.

Careful and complete studies of costs and the effects of government-owned pharmacies upon the economy would be needed before any such system is established.

CAPITATION REIMBURSEMENT

In recent months, it has been suggested with growing emphasis that the Federal Government should help provide greater opportunities for the development of new health care delivery systems to provide better health for citizens, along with more efficient and effective use of health personnel and facilities.[47] The use of a capitation reimbursement system—that is, payment based on the number of patients served—has been proposed as one approach in this direction.[48] Two alternative methods could be used in a drug program: (1) capitation to medical groups and (2) capitation to pharmacies.

Capitation Reimbursement to Medical Groups. A lump sum payment of the estimated yearly medical expenses of persons choosing this reimbursement plan could be made by the program to physicians organized in a medical group practice. The group would be responsible for the full medical care, including provision of drugs, of these recipients during the year. The group would presumably provide all necessary care at the lowest practical cost in order to obtain maximum total net income. The incentive to provide high quality care at low cost would extend to the prescribing habits of physicians, and should result in a more rational drug therapy program.

Medical groups could provide drugs for their recipients in one of several ways. They could, for example, allow patients the freedom of choice of all pharmacies in the area. The outlet selected by each beneficiary would dispense the prescription to him and be reimbursed at the "usual or customary" fee by the medical group. The only cost savings under this plan would result from a more rational approach to prescribing. On the other hand, it could provide the impetus for inflationary price increases by such vendors which would be borne by all purchasers, public and private alike.

A second alternative would allow the recipient the right to select any of a group of contract pharmacies which would provide the prescription services. The medical group would enter into agreements with these pharmacies to provide prescriptions to beneficiaries on an established reimbursement schedule. Pharmacies could be required to bid upon the right to provide the service.

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[47] Department of Health, Education, and Welfare: "A Report to the President: Medical Care Prices," U.S. Government Printing Office, Washington, D.C., 1967, p. iii.

[48] Feldstein, Paul J.: "A Proposal for Capitation Reimbursement to Medical Groups for Total Medical Care," in Reimbursement Incentives for Medical Care, U.S. Social Security Administration, Washington, D.C., March 1968, pp. 87–103.

A third alternative would be provision of pharmaceutical services within the confines of the medical group practice. Investments in inventories would be less than in community pharmacies, since the pharmacy need carry only those products which would be prescribed by the group physicians. Effective cost control mechanisms could be applied. The shifting of costs to private patients would not be a factor. The benefits of rational drug therapy would be available under this alternative as in the other two approaches.

Under this plan, the patient would lose his right to select his own pharmacist. Several State laws may raise barriers to such an approach. Where possible, however, experimentation with the inclusion of pharmacists as members of the medical group deserves consideration.

Capitation to Pharmacies. Lump sum payments to cover the estimated yearly drug expenses for each program beneficiary could be made to selected pharmacies which choose this method of reimbursement. Such an approach is now used in the Belgian national drug program.[49] Such a method, however, could not be applied to the small-scale independent pharmacy, since drug expenses can vary greatly for the elderly, and the typical small independent pharmacy would probably be unable to withstand the losses that would result if its patients have unusually high utilization rates. Capitation would be more feasible for large chain store pharmacies, in which the risk can be spread over a large number of outlets in many geographical areas.

This type of capitation might be used to promote the establishment of group practice pharmacies or pharmacy groups. Such practices have been under study by pharmacists during the past few years as a means of providing high quality pharmaceutical services at low cost.[50] Combining several small pharmacies into one pharmacy providing only pharmaceutical services could achieve improved efficiency in three areas: first, the investment in inventory would be lower than the total investment of several smaller outlets; second, operating expenses would be less than the total expenses of several smaller pharmacies; and third, the pharmacists' time could be more effectively utilized.

Although capitation for group pharmacy practice would offer incentives for greater efficiency, it would not provide incentives for rational drug prescribing by physicians. It is possible—and has been recommended[51]—that pharmacists in a community could work in conjunction with physicians to develop a local formulary. Physicians would authorize pharmacists to dispense a therapeutically equivalent drug listed in the formulary in place of a brand-name item—a practice now used in many hospitals. The pharmacists' investment in inventories would thus be reduced, with high quality drugs available to patients.

The Delaware Pharmaceutical Association and the Delaware Medical Association have recently joined to establish such a formulary system for use throughout the State.[52] As a start, a formulary containing between 10 and 40 drugs will be prepared by a committee composed of four pharmacists, four physicians, one dentist, and one osteopath, under the chairmanship of a public member. The committee will submit the list of acceptable brands to the local wholesalers, who will then seek bids on the products from manufacturers. Those manufacturers submitting the accepted bids will provide the drugs for a six-month period, whereupon new bids will be sought. A physician will indicate on the prescription that the accepted formulary drug may be used in place of the brand-name drug he has prescribed. Savings resulting from the lower acquisition cost will be passed on to the patients, both public and private.

Other steps leading to rational drug therapy under a capitation program could be taken through joint pharmacist-physician utilization review committees. The capitation method, however, is not likely to generate prompt or complete claims data essential for effective review.

Administrative costs under any of the capitation systems discussed here would be relatively low. Individual drug claims would not have to be processed by the government. Yearly reviews of cost and utilization would be required in order to determine the proper capitation sum. Verification of services rendered would not be necessary, and vendor audits would be held to a minimum.

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[49] "Current American and Foreign Programs," *op. cit.*, pp. 180–183.

[50] Dee, Donald A.: "Group Practice in Pharmacy." Journal of the American Pharmaceutical Association (NS) 8: 293–295 (1968).

[51] Kunin, Calvin M.: Statement in U.S. Senate, Select Committee on Small Business, Subcommittee on Monopoly: "Competitive Problems in the Drug Industry," U.S. Government Printing Office, Washington, D.C., 1967, Part 2, p. 730.

[52] Anderson, Mary Louise (Delaware State Pharmaceutical Association): Personal Communication, December 1968.

OTHER FACTORS

All of the reimbursement systems considered here have two limitations which require further study and action in order to improve the quality of care and enhance vendor efficiency. Although these factors are in large part out of the control of vendors, they are critical to an efficient drug program.

Rational Drug Therapy. None of these reimbursement formulas will in themselves greatly improve the drug therapy of recipients, since this factor remains almost exclusively in the domain of the prescriber, who is usually not the dispenser. No reliable incentives can be developed in these systems, for example, to reduce the quantities of drugs prescribed by physicians for patients receiving drug insurance benefits.

Although physicians have the major responsibility for developing rational drug therapy,[53] there appears to be much that can be accomplished by physicians and pharmacists—working in cooperation—to minimize such types of irrational drug therapy as these:

- The use of drugs in excessive amounts, or for excessive periods of time, or inadequate amounts for inadequate periods.
- The simultaneous use of two or more drugs without appropriate consideration of their possible interaction.
- Multiple prescribing, by one or several physicians, of drugs which may be unnecessary, cumulative, interacting, or needlessly expensive.
- The use of a costly product when an equally effective but less expensive drug is available.

Manufacturers' Packaging Policies. Pharmaceutical products in the form of tablets and capsules are generally packaged by the manufacturer in 100's, and in the case of fast-selling items, in 500's, 1,000's and even 5,000's. These packaging sizes usually reflect the needs of the pharmacist in terms of accessibility, storage space, and the prescribing habits of physicians. Considering the variety of dosage forms and the multiplicity of drug products on the market today, the pharmacist apparently cannot afford to stock thousands of containers of prescription drugs.

A cost-saving factor is clearly involved. If the price of a larger quantity of a drug product is less per unit, the pharmacist may purchase the larger amount, even if this means that it will take somewhat longer to sell. This practice is especially common in the case of "standard drugs," i.e., the well-known or widely-used maintenance drugs.

Another cost factor may also be involved. Many physicians write prescriptions for numbers of tablets or capsules that may have no relation to the numbers currently packaged by manufacturers. For example, where a standard package contains 100 tablets, the prescriptions call for dispensing them to individual patients in such numbers as 6, 21, 35, 50, or even 105. To fill such prescriptions, the pharmacist must take the time to count out the required number of units, put them in an appropriate container, and label the container—an operation which obviously represents a major expense, and which also presents at least a chance for error.

To cope with this situation, some manufacturers have agreed to prepackage their products—especially their fast-moving items—in sealed, labeled containers holding, for example, 10, 20 and 100 units, respectively. In filling a prescription, the pharmacist dispenses the requisite number of each of these prepackaged, prelabeled containers to give a total most closely approximating the number specified in the prescription. (In the case of certain critical drugs, such as narcotics, it may be necessary for the pharmacist to count out and dispense only the prescribed number of units.)

This technique is now being used by some European drug manufacturers. For several years, some of these manufacturers have followed the "unit-dose" system of providing such prepackaged drugs for patients in hospitals, clinics and other mass-dispensing outlets. In the United States, the "unit-dose" system, the use of disposable syringes, and similar techniques to save personnel time and cost have been perfected for hospitals by a number of major drug companies. Even pharmacies have benefited to some extent through the acquisition and dispensing of labeled single-dose drug products, manufactured in continuous strips and hermetically sealed in foil.

The use of these smaller packages would increase the cost per tablet or other unit; however, the higher acquisition costs should be more than balanced by savings in time and manpower formerly used in preparing small-unit prescriptions from large-unit bulk storage, and in labeling the containers. Program savings would result from such techniques, and dispensing errors could be minimized.

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[53] "The Drug Prescribers," *op. cit.*, p. 3.

CHAPTER 5
METHODS OF PATIENT COST-SHARING

Traditionally, several techniques have been applied in insurance programs to assure that those actually receiving the benefits will share in the costs. Among these are deductibles, co-insurance, and a form of the latter, co-payment—sometimes used alone, sometimes applied in combination.

In addition to their usefulness as cost-sharing methods, and as approaches to reduce program costs in general, these techniques are believed by some to have value in preventing needless abuse of the program, and in instilling a "sense of responsibility" among the potential users.

Deductibles

Customary in many types of insurance—health, automobile collision, fire and others—is a provision requiring the policy holder to absorb a certain amount of loss during a given period of time before benefits are available.[a] The number of dollars he must pay represents the so-called deductible.

If a deductible were to be incorporated in a drug insurance program, it would mean that the patient would have to incur the total cost of prescription expenses up to a certain point before insurance benefits would provide financial assistance. If, for example, a deductible of $60 per year were established and the average prescription cost were $4, the typical patient would pay the total cost of 15 prescriptions from his own resources before he obtained any aid from insurance coverage. Individuals purchasing fewer than 16 typical prescriptions annually would receive no benefits.

It should be noted that the use of deductibles in a drug insurance program would be markedly different from their use in such programs as so-called major medical policies. In the latter, where the deductible amount is set at $100, $250, or $500, the patient may exceed the deductible in one serious illness or one hospital stay, and would need to produce only one or two receipted bills as evidence. In a drug program, however, he may be required—depending on the size of the deductible—to maintain records on perhaps 12 to 25 bills.

Similarly, the carrier's expenses of handling such bills may not be insignificant. In general, the cost of reviewing 12 bills, each for a $4 prescription—to demonstrate that the deductible requirement has been met—may be 12 times as high as processing a single hospital bill for $500.

"High Deductible" Approach. For a Medicare program, consideration has been given to a proposal under which virtually all legend drugs would be covered, subject to a $100 annual deductible, and with a co-insurance of 20 percent to be paid by the beneficiary on drug expenses above that amount. Beneficiaries would be responsible for keeping records and submitting claims for reimbursement, and would be permitted to submit claims only after accumulating charges which equal the deductible amount.

Under this approach, the pharmacist would be asked to certify that a drug was available only on prescription and was provided for the use of the named beneficiary. The pharmacist's certification would appear on each receipt for a covered drug.

The beneficiary would collect and submit his receipts for covered drugs in a pre-addressed envelope furnished by the Social Security Administration. Reimbursement would be made directly to the beneficiary, on an indemnity or "reasonable charge" basis.

In comparison with comprehensive coverage, this "high deductible" proposal would result in substantial reductions in both program costs and claims levels. Under one set of assumptions,[b] it is estimated that the cost of the proposal would be $405 million in the first year of operation, and that reimbursement would be made for about 100 million claims in that year—rather than $1.6 billion and 443 million claims with a comprehensive approach without deductibles. If the benefit were provided under Part A, it is estimated that the level-cost of the proposal would be 0.14 percent of taxable payroll (based on the "high-cost" estimate and exclusive of administrative costs. As shown below, however, using different assumptions,[c] the insurance program administrator would have to process more than twice as many prescriptions as would be required under such a high deductible.

Of the various methods of limiting the administrative burden of a drug benefit, this proposal could be designed in a way that would permit the highest degree of administrative simplicity. Not only would claims levels be greatly reduced, but a large part of the recordkeeping burden would rest with the beneficiary, rather than with the Social Security Administration. Moreover, the Administration would not necessarily have to enter into agreement with the 54,000 community pharmacies or with the approximately 3,000 other dispensers of drugs. The process of negotiating such agreements and of maintaining ongoing relationships with participating drug vendors would obviously result in a substantial workload. An additional consideration is that drug vendors would not be required to keep records for reimbursement purposes.

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[a] The patient obligation in these commercial applications may be closer to a co-payment provision than a deductible, since the factor of time may not be related to the amount paid by the policy holder.

[b] See Appendix A.

[c] See Chapter 9.

The main drawback to an approach involving a $100 deductible is that, for a beneficiary with heavy drug expenses and limited resources, $100 is a very large amount of money, and a deductible of this size would mean that drug expenses would remain a real hardship to many beneficiaries. While a lower deductible amount could be established, this would result in increased workloads and program costs.

For example, a $75 annual deductible with a 20 percent co-insurance, provided under Part A, would involve benefit costs of about $535 million in the first year of operation, with reimbursement being made for an estimated 140 million prescriptions, and an estimated level-cost, exclusive of administrative expenses, of 0.18 percent of taxable payroll.

If the deductible were $50, assuming no other changes in the provisions just listed, benefit costs would be $710 million, reimbursement would be made for an estimated 190 million claims, and the level-cost would be 0.25 percent of taxable payroll.[a]

Another drawback to a high deductible approach is the difficulty that beneficiaries would have in keeping track of their drug expenses. Under this approach, assuming an average cost of $4 per prescription, the beneficiary might have to accumulate as many as 26 prescriptions before he could be reimbursed for any of his drug expenses. Experience with the present $50 annual deductible under Part B indicates that Medicare beneficiaries have great difficulty keeping track of their medical bills, especially those for small amounts, and supports the inference that the higher the deductible amount, the more serious the problems.

Furthermore, to a great extent the administrative and cost advantages of such an approach are based on the assumption that the administering agency would be engaging in only a minimum amount of claims administration. For example, since validity of a claim would rest primarily on a pharmacist's certification that the receipt was for payment of a prescription drug dispensed to a given beneficiary, there would be opportunity for abuse of the benefit—such as beneficiaries procuring drugs for other members of their families or for their neighbors. The additional expenses involved in preventing such abuse would detract from the administrative and cost advantages of the proposal.

Co-Insurance

If the patient is required to pay a portion of the cost of each benefit, the term "co-insurance" is used to designate the obligation. For drug insurance, the beneficiary would be expected to pay a specified percentage of the cost of each prescription. In health insurance, proportions of 20, 25, or even 50 percent have generally been used, and such percentages could be considered under a drug program.

Another widely-used variation of co-insurance is "floating co-insurance," accomplished simply through the establishment of an indemnity fee schedule, with the reimbursement specified for each drug product or prescription. The levels of benefit payment could be set so that, in effect, an average co-insurance charge (for example, 20, 25, or 50 percent) would be met by all claimants together. In specific instances, patients might find that their out-of-pocket expense could range from nothing (with the indemnity schedule covering the full amount) to more than half (even under the 20-percent assumption) of the actual price.

An indemnity schedule thus makes it possible to (1) fix the program's liability in relation to the cost of each drug product or prescription, and (2) ignore actual price by making the patient cover any difference between the scheduled benefit and the specific price charged. Floating co-insurance of the indemnity allowance type concentrates the risk of varying or excessive market prices entirely on the patient.

Co-Payment [b]

Another variation of cost-sharing per benefit received is co-payment. This involves a flat charge—for example, $1.00, $1.50, or $2.00—which must be paid by the patient on the price of each prescription. This approach has been used at one time or another in such national drug programs as those in Australia,[1] Germany,[2] and Great Britain.[3]

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[a] See Appendix A.

[b] Although co-payment may be viewed as one form of co-insurance, the two will be considered separately here, with co-insurance referring to cost-sharing on a percentage basis and co-payment referring to a flat dollar-and-cents charge.

The relative impacts of co-insurance and co-payment are illustrated in the following table:

Retail Drug Price	20% Co-Insurance		Co-Payment of $1.50	
	Program Expense	Patient Obligation	Program Expense	Patient Obligation
$1.50	$1.20	$0.30	----------	$1.50
3.00	2.40	0.60	$1.50	1.50
4.75	3.80	0.95	3.25	1.50
6.00	4.80	1.20	4.50	1.50
8.29	6.63	1.66	6.79	1.50
10.00	8.00	2.00	8.50	1.50

If the primary goal of drug insurance is to help those persons with large drug expenses—usually involving many prescriptions—then the co-payment factor would probably be low, say $1.00 per prescription. If the primary goal, however, is to concentrate the out-of-pocket financial burden more directly on heavy users, then the co-payment could be set higher, such as $1.50 or $2.00.

A flat co-payment charge levied against each prescription order has two possible limitations:

1. The percentage of total drug cost paid by the consumer falls sharply as the price of the prescription rises. For example, a $1.50 co-payment charge on a $3.00 item represents a 50-percent patient contribution, while on a $15 item it represents only a 10-percent contribution. It may be observed that vendor reimbursement according to a percentage markup[4] would exaggerate this characteristic, while reliance on a flat dispensing fee[5] would minimize it. Consequently, from the point of view of assuring a more equitable economic burden on all drug users, it may be expected that a flat co-payment charge per prescription order would be used in conjunction with a flat dispensing fee. Similarly, a percentage co-insurance charge would tend to be more appropriate if pharmacists' services were paid for through a percentage markup over cost.
2. If the program uses a flat co-payment charge, a physician could attempt to help a patient by ordering a drug in larger quantities than actually needed, and thereby increase program cost. This tendency would be present if the drug program used a percentage markup formula to cover vendor overhead expenses. With a flat dispensing fee, however, the reverse effect would occur, especially in the case of maintenance drugs needed for chronic illness; program costs would tend to fall, and patient out-of-pocket expenses would be held at a minimum. For elderly patients, this latter approach would be especially important.[6]

Other Methods

Deductibles, co-insurance, and co-payment are not the only cost-restricting methods that can be used in a drug insurance program. An annual maximum on reimbursement is another such device. Moreover, a variety of controls may be found in some of the current programs used in this country and abroad.[7] For example, the doctor may be precluded from prescribing a quantity of any drug that costs more than a fixed sum, such as $10.00. A variation of this restriction takes the form of requiring the physician to obtain prior approval on an expensive prescription before it will be covered by the insurance program.

These approaches are not treated in this chapter because: (1) they seem to place unscientific barriers before the physician attempting to treat a patient with appropriate drug therapy, (2) they tend to thwart the development of more appropriate techniques for controlling the qualitative problems associated with prescribing, and (3) they assign a role to financial constraints that presumably should be borne by the revenue sources of the insurance program.

Relative Advantages

Numerous advantages have been attributed to the use of deductibles, co-insurance and co-payment in health insurance in general. The more important are discussed below.

1. *Limitation of Program Cost.* A primary effect of deductibles, co-insurance, and co-payment would be reduction in the total value of claims,

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[1] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968, pp. 137 *et seq.*

[2] *Ibid.*, pp. 193 *et seq.*

[3] *Ibid.*, pp. 175 *et seq.*

[4] Task Force on Prescription Drugs: "The Drug Makers and the Drug Distributors," U.S. Government Printing Office, Washington, D.C., 1968, p. 63.

[5] *Ibid.*, pp. 63, 66–67.

[6] Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, p. 35.

[7] "Current American and Foreign Programs," *op. cit.*

and thus a reduction in patient premium or tax contributions. The corollary, however, is that more of the cost must be borne by the patient who requires treatment.

2. *Control for Unknowns.* Deductibles, co-insurance and co-payment could be applied on a temporary basis to control expenses during the early years of a program, when utilization and charges may not be predictable with adequate accuracy.

One of the important factors here is the lack of experience with drug insurance coverage for use as a basis for predictions. The adaptation of beneficiaries to a new method of financing is likely to bring adjustments which cannot be accurately foretold. Utilization may be far greater than expected. Appropriate cost-sharing approaches could cushion the effect of such utilization during the first few years of a program.

3. *Incentive to Proper Utilization.* It is widely held that cost-sharing would give patients an incentive to use the program prudently, avoiding excessive services and seeking low-cost alternatives. For example, in an extensive review of deductibles, Charles Hall has reported on the almost universal feeling that a deductible will reduce utilization and thus serve to control the pressure on premium charges. He has noted the paucity of data to support this position.[8]

Implicit in the control function philosophy is an assumption that cost-sharing discourages "unnecessary" utilization without impeding "necessary" utilization. There is no available empirical or theoretical evidence to support such a contention. Moreover, if necessary treatment is postponed because of financial constraints, health care will be inadequate and eventual claims upon the drug program or a related health insurance program may be larger than if care had been received when originally indicated.

It should also be noted that use of a deductible alone—that is, without co-insurance—may induce the beneficiary to increase his utilization in order to "get his money's worth" out of his premium expenditure.[a] Thus, once he has hurdled the deductible barrier, the patient may feel that he can use the program freely without any limitation.

A deductible may provide an incentive for the patient and the vendor to collaborate in falsifying records. Some claims, for example, could be submitted to show a larger value than the actual cost of the service, thus signaling that the deductible had been met. The administrator of a drug program would have to examine the charge for each claim associated with the deductible if he were to ascertain whether such inflated figures had been submitted. Where a relatively small deductible is involved, most patients could predict beforehand that they were likely to break the deductible limit, and might be tempted to indulge in this kind of fraud. Furthermore, a patient might be more inclined to apply pressure on his local pharmacist to engage in such falsification than, for instance, to induce a hospital administrator to alter a bill for hospital services.

The extent to which co-insurance will motivate patients to seek low-priced drug products may be influenced by a number of possible conditions. If the insurance program pays the vendor according to a fee schedule, co-insurance would not provide much inducement to the patient to search for discount prices. If the program sets reimbursement in terms of "reasonable charges," co-insurance might perform an economizing function when (1) the buyer feels that he has some discretion concerning the purchase of the prescription, (2) he knows of alternative retail outlets where lower price differentials are available, and (3) he is willing to base his decisions on the economic distinction created by the co-insurance. On the other hand, if the purchaser selects a vendor for reasons that do not give much weight to product prices, co-insurance is likely to exert little influence.

Moreover, the size of the co-insurance as related to prescription price can be expected to influence the willingness of a patient to shop for the lowest-priced item. For example, with a 20-percent co-insurance rate and the existence of a prescription price of $4.00 in one outlet and $5.00 in another, the difference in patient cost—20 cents—would probably not induce many patients to shop for low prices. Only where the charge is large—e.g., $50 or more—and/or where the co-insurance is set at least as high as 50 percent, where alternative vendors are available, where the prescription is not needed urgently, where prices do indeed vary significantly, and where the patient is prone to act rationally—only then does the economizing feature of co-insurance seem to have any potential for controlling program cost.

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[8] Hall, Charles P., Jr.: "Deductibles in Health Insurance: An Evaluation," Journal of Risk and Insurance 33 (No. 2) :257 (June 1966).

[a] This is illustrated by the experience of one very large carrier in the health insurance field. The *lowest* loss-ratio was found among those groups where the employer paid the entire premium charge and the *highest* ratio was found among groups where the employee paid the entire premium. An intermediate ratio characterized those groups where the employers and employees shared in meeting the premium expenses.

4. *Payment of Larger Bills.* With application of a deductible, insurance funds presumably would be used to pay only for large health care bills, thus concentrating the benefit where it is most needed. The burden of any particular deductible or non-insured amount would, of course, be greater for beneficiaries with low incomes.

5. *Avoidance of Small Claims.* One basis for supporting the use of a deductible is the possibility that it would enable the carrier to avoid processing many small claims—for instance, those under $10—which otherwise would flow through the insurance mechanism. Since the cost of claims processing often bears little relationship to the dollar value per claim, overall administrative expenses could be kept at a minimum if the large volume of small claims were handled by the patient himself. The patient would sustain these expenses, which presumably he could meet best, and insurance—utilizing a deductible or a high flat co-payment—would be reserved for the larger obligations.

In the case of drugs, however, essentially all claims would be small, as indicated by the distribution of probable charges for prescription orders shown below:[a]

Prescription Price	Percentage Distribution of All Prescriptions	
	If retail price established on basis of 40 percent markup	If retail price established on basis of $1.75 dispensing fee
Total	100	100
Under $2.00	24	1
$2.00 to 2.99	24	26
3.00 to 3.99	19	36
4.00 to 4.99	12	21
5.00 to 5.99	9	9
6.00 to 7.99	7	5
8.00 to 9.99	3	1
$10.00 and above	2	1

Relative Disadvantages

There are a number of reasons for questioning heavy reliance on deductibles and co-insurance. Some of these have been suggested above in the analysis of the advantages.

1. *Economic Burden on Users.* With cost-sharing, the economic burden would be concentrated particularly on those utilizing substantial amounts of prescription drugs. Deductibles, co-insurance and co-payment would tend to shift health care expenses from an insurance program—which is an effective means of spreading the risk—to the patient using the service, who would thus absorb more of the risk.

It is possible to provide special relief from co-payment (but not from deductible) provisions to persons with large drug bills. For example, the program could include "catastrophic coverage" or a maximum co-payment feature—say, $150 per year—beyond which the patient would either be exempt from any subsequent co-payment charges during the remainder of the year, or be reimbursed directly by the program at the end of the year.

Another but more complicated approach would be sliding-scale co-insurance which would vary the proportion of user responsibility with the amount of total cost. This is a common approach in casualty insurance, where in some instances underwriters may reimburse even more than 100 percent of losses in excess of a given amount. For a drug program, proportions might be set at 50 percent of the first "x" dollars, and 75, 80, or 100 percent of additional amounts. Again, this extra benefit could be administered using temporary eligibility devices, or separate, periodic beneficiary reimbursements. All such variations would increase the complexity of administration.

2. *Unequal Economic Burden on Users.* The problem of paying deductible, co-insurance and co-payment charges cannot be met with equal ease by all participants in an insurance plan. Moreover, especially for those requiring treatment for acute conditions, the economic burden is likely to be concentrated in a short period of four to six weeks. Only if all medically indigent persons were protected fully by Title XIX coverage would this factor cease to be important.

In his comprehensive analysis of health economics, Klarman has called attention to the fact that "co-insurance is not a deterrent to extravagent spending by the well-to-do while it imposes excessive burdens on the average family."[9]

3. *Under-Utilization.* As suggested above, necessary drug utilization may be curtailed as a by-product of efforts to discourage unnecessary drug consumption through deductibles, co-insurance,

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[a] Derived from basic data supplied by Joseph McEvilla, University of Pittsburgh, 1968.

[9] Klarman, Herbert: "The Economics of Health." Columbia University Press, New York, 1965, p. 37.

and co-payments. Thus, cost-sharing could serve to counteract one of the presumed goals of the program—that is, to help individuals recover from illness by removing economic barriers. This underutilization would probably result in higher expenses at a later date under either or both hospital insurance or supplementary medical insurance.

4. *Incomplete Records.* The deductible or a high co-payment would permit certain claims to by-pass the system, and accordingly all utilization records would be incomplete, making needed utilization review difficult or impossible. Co-insurance, "floating co-insurance," or a moderate co-payment without the deductible, however, would permit collection and processing of all claims, thereby providing more reliable program statistics.

5. *Incentive for Fraud.* Both deductibles and co-insurance could provide an incentive for patients and vendors to collaborate in submitting inflated bills. Co-insurance coupled with inadequate consumer knowledge would also permit dispensers to "overcollect" the beneficiaries' share.

6. *Bad Debts.* Certain vendors may encounter a problem in collecting deductible and co-insurance charges unless other controls were established. The cost of collecting unpaid debts resulting from the application of co-insurance in particular may inflict an expense on the vendor that would be greater than the value of the obligation.

7. *Wrap-Around Coverage.* The use of complementary coverage to fill gaps created by deductibles, co-insurance and co-payment may defeat the purpose of controlling utilization, while at the same time creating other problems. If elderly patients should be confronted with many complementary contracts sold by private carriers, they would find it difficult—and most would find it impossible—to evaluate the relative merits of the various packages. If the elderly person should purchase such an insurance contract, he may find that he can do so only at nongroup rates, and would probably pay rates that are higher by some 20 to 50 percent than if such coverage had been available on a group or governmental basis.

8. *Vendor Reimbursement and Patient Responsibility.* Either co-insurance or co-payment can be combined with either patient or vendor reimbursement, but the use of an annual deductible would probably preclude a system of vendor reimbursement.

With beneficiary reimbursement and use of a deductible, the patient would need to keep records on his drug expenses until the deductible is exceeded. An implicit cost of some magnitude would be involved, both on the part of the patient and on that of any agency that from time to time must give patients an explanation of the nature of the deductible requirement. In addition, considerable time would be required on the part of the pharmacist to furnish claim information to the patients, many of whom would not exceed the deductible level. This burden on the vendor could also contribute to higher drug prices.

9. *High Administrative Expense.* In addition to precluding vendor reimbursement, use of a deductible could result in high administrative costs because of the additional expenses associated with review of deductible claims. Less burdensome administrative expenses would presumably be required in reviewing claims involving co-insurance or co-payment.

Arbitrary Program Goals

In the design of any drug insurance program, consideration would obviously be directed toward (1) whether or not—in view of the relative advantages and disadvantages—such cost-sharing features as deductibles, co-insurance, and co-payment should be employed, and (2) whether the deductible level should be set, for example, at $25, $50, $75, or $100 a year, the co-insurance percentage at 10, 20, 25, or 50 percent, or the co-payment at $1.00, $1.50, $2.00, or some other figure.

At the same time, consideration would be needed to determine whether the primary goals of such cost-sharing approaches should be reduction of program expenses and maximum administrative simplicity, or the improvement of health care and the provision of the highest quality of care at the lowest practical cost.

Carrier Experience

The experiences of organizations in the health insurance field that have applied deductibles, co-insurance, and co-payments to their operations may be of some importance. Probably the most comprehensive and current evaluation of this subject was published by Hall in 1966. He concluded that the effect of these "provisions in health insurance contracts on the utilization of health care services and facilities is extremely difficult to quantify." [10] Reference was made to a number of other factors that could influence the outcome, including the breadth of the underlying coverage and the range of applicability of the deductible and percentage participation provisions.

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[10] Hall, *op. cit.*, p. 262.

A number of carriers have initiated programs providing general coverage and subsequently have introduced deductible and/or co-insurance features to help control rising costs. If utilization is reduced, however, a scientific basis is seldom available to support the conclusions and inferences that are made. For example, such studies fail to take account of the fact that the early years of an insurance plan are frequently unique. Only when a program matures and utilization stabilizes can an assessment of co-insurance and deductibles be undertaken. Often such factors as inadequate supplies of goods or services, rising prices, changes in patient needs, and the like may not be adequately recognized.[a]

Because of the importance of intervening variables, it may never be possible to make a complete interpretation of these cost-sharing devices. In order to conduct a cross-sectional study, it would be necessary to set up control groups and experimental groups as determined by scientific selection techniques. The research design would have to take account of such factors as the number and type of drug outlets, the type of specialists in the area, and economic characteristics of the patients.

It would have to be assumed further that the general distribution of illnesses by number and type, the attitudes toward prevention and treatment, and so on, would be similar from one group to the other. None of the studies regarding deductibles, co-insurance, and co-payment has endeavored to provide control of such variables, and therefore none can properly attribute changes in utilization to these fiscal measures alone.

The predictability associated with the use of deductibles, co-insurance, and co-payments is not high. For example, the Province of Saskatchewan levied a 20 percent co-insurance charge on prescription drugs furnished to welfare patients in 1948, and, because of increasing program cost, raised the figure to 50 percent in 1959. The Royal Commission on Health Services noted that "it is worth recording that these co-charges have not had the deterrent effect originally hoped for, even though they were followed by an overall reduction in drug utilization."[11] Variations, moreover, did occur in relation to age, sex, and degree of urbanization. In one group—males, aged 25–44—utilization actually *rose* despite the sharp increase in co-insurance.

One large business organization, after lowering the deductible for one group of its employees, while maintaining it for another similar group, concluded that "utilization is importantly affected by factors other than deductibles."[12] Further, the experience of an insurance firm that had instituted co-insurance and deductibles for five of its clients was summarized as follows: "The results were inconclusive. Two cases showed a more favorable financial experience, two showed continued deterioration, and one little if any change."[13]

In North Carolina, a $1.00 co-payment was applied to each prescription in the State's welfare drug program.[14] In a nine-month period before use of the co-payment, with an average of 171,000 persons at risk, 393,433 drug claims were presented for a total cost of $4.9 million. In a comparable nine-month period after the change, with 169,400 persons at risk, the number of claims *rose* to 398,439 but the total cost dropped to $4.1 million.

In another effort to control drug program outlays, the British Government instituted a flat charge of one shilling (14 cents) for each prescription.[15] Costs continued to rise because many physicians offset the intended effect by including two, three, or four drugs on each prescription, and the flat charge was thus spread over several items instead of one. (It is well to note that the physician may change his prescribing habits even though a financial deterrent is applied not to him but to the patient.)

The government then attempted to gain control over the situation by levying the co-payment charge against each item on the prescription. This had less than the desired effect, since again many physicians—instead of prescribing their customary dosages—wrote orders for much larger quantities, such as 200 or 400 units. The flat charge technique was again circumvented.

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[a] Also see *Blue Cross Reports*, October 1968, for a discussion of the effects of deductibles upon hospital utilization.

[11] Royal Commission on Health Services: "Provision, Distribution and Cost of Drugs in Canada," Department of National Health and Welfare, Ottawa, Canada, 1964, p. 80.

[12] Hall, Charles P., Jr., *op. cit.* p. 260.

[13] *Ibid.*

[14] "Current American and Foreign Programs," *op. cit.*, pp. 84–86.

[15] *Ibid.*, pp. 178–179.

On February 1, 1965, the government abolished the co-payment levy. Analysis of the experience just before and after this change in policy led the actuary of the U.S. Social Security Administration to observe that "there has been an increase of 15 percent in the number of prescriptions, apparently because of the elimination of the cost-sharing payment." [16] Whether this trend might have continued is unknown, since co-payment (2 shilling 6 pence) was reintroduced in January 1968.

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[16] Myers, Robert J. (Social Security Administration): Personal Communication, 1968.

CHAPTER 6

PROGRAM ADMINISTRATION

Because of the high volume of claims that would occur in almost any type of Medicare drug insurance program, administrative costs could be very large in comparison with benefits. Some of the related administrative goals and problems are discussed in this section.

General Considerations

Under any type of program, the major administrative cost element would be that directly related to claims processing. Claims processing costs may be defined to include all expenses of (1) recording claims information, (2) claims submission, (3) the administrator's claims-receiving and control activities, (4) determination of product, vendor and prescriber eligibility, (5) determination of benefits payable, and (6) production and distribution of the proper payment forms and equipment.

The non-claims-processing or general overhead expenses that are also part of administrative costs include those involved in determination of patient eligibility, field audits, utilization review, statistics, program evaluation, continuing public and professional relations and education, and other activities required for effective and conscientious administration.

If the average drug benefit should be $4.00 per prescription, an administrative expense goal of 5 percent would imply total administrative costs of 20 cents per claim processed. Perhaps two-thirds—about 13 or 14 cents per prescription—might be needed for direct claims processing costs, one-third for general overhead administrative costs. Experience in at least one of the State drug programs[1] suggests that, at recent price levels, a goal of approximately 13 cents per claim for processing would not be unrealistic after the initial period of operation.

Control of Claims Processing Costs. Claims processing costs would almost certainly be higher if beneficiaries rather than vendors were reimbursed. A beneficiary reimbursement system would need to recognize the postage and other costs of the more numerous benefit checks which would be involved if the program dealt directly with a potential 20 million beneficiaries instead of perhaps 60,000 pharmacies and other vendors. In addition, reporting of claims by beneficiaries would not only prohibit application of source data automation but also complicate any administrative efforts to predict and manage the volume of claims.

Should a co-payment charge be levied on each prescription dispensed, the ratio of administrative cost to benefits paid would rise as the size of the average payment falls, with no change in total administrative costs. For example, if a $1.00 co-payment were established, and the average prescription price were $4.00, as assumed above, an administrative expense of 20 cents per prescription would represent an administrative cost of 6⅔ percent rather than 5 percent. If both deductible and co-insurance features were included, the actual administrative cost per claim processed would also be higher.

Expenses would also be higher if many prescriptions required checking to determine if the drugs were covered by the program—especially if a mandatory formulary were used. In the same way, restrictions based on such factors as diagnosis, disability status, and quantities dispensed would add to administrative expense.

Control of General Overhead Costs. One of the most difficult and costly aspects of operating a drug program is determination of patient eligibility.[a] It is exceedingly expensive, for example, to check eligibility at the time each drug service is received. Further, under a system based on vendor reimbursement, either the program or the vendor must sustain the cost whenever a prescription is dispensed to an ineligible recipient.

Under any reimbursement approach, patient eligibility problems could be minimized if individuals were permanently certified as eligible for drug benefits. This could be readily accomplished for all insured elderly individuals if drug benefits were provided under Part A of the Medicare program, although there would still be need for continuing spot checks to ensure that the dispensed prescriptions were actually for the use of the eligible beneficiary.

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[1] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968, pp. 61, 67.

[a] See pp. 10, 11.

Automated Data Processing System. It appears evident that maximum efficiency in claims handling can be best achieved through use of an automated claims processing system.

Most insurance programs are plagued by a wide discrepancy between claim liability calculated on a paid basis and program expenses calculated on an incurred basis. This problem would be minimized under a system in which the dispensing of the drug and the receipt of the completed claim by the central computer would occur without delay. With the use of electronic devices now on the market, or capable of being produced, the vendor could be tied into a system making it possible for central computers to receive drug claim information in machine-readable language within a few hours—possibly within a few minutes, or even seconds—after completion of the transaction.

Operation of an input device could require that the patient's identification card must be inserted into the unit, along with a comparable identification card for the drug product, thus helping to speed claim submission as well as to ensure accuracy.

With an appropriate automated claims processing system, prompt vendor payment would be possible. Such a system would, for example, permit the reimbursement of low-claim-volume vendors every 15 days, and of high-volume vendors every 10 days. The program administrator could further speed reimbursement by forwarding the vendor's check directly to his designated banking account, while simultaneously sending directly to him the itemized voucher covering all paid claims.

(If reimbursement were to be made to the beneficiary rather than the vendor, it would be preferable from the point of view of administrative costs to make infrequent payments, thus having lengthy periods between expenditure and reimbursement.)

It is even possible that electronic devices might be used to print the prescription label as a by-product of preparing the drug claim.[a]

The system should ideally be designed to minimize the amount of time that the vendor must spend in preparing the drug claim. An insurance program presenting an additional responsibility of any magnitude for some 25 percent of the typical pharmacist's business would require the pharmacist to find a reasonably efficient method of handling the claims process. The paperwork problem would be further aggravated if as much as 70 percent of the pharmacist's business involved third-party payment, and if the polyglot of traditional claims forms were still used.

A beneficiary reimbursement system would require pharmacists to supply beneficiaries with a "proof of purchase" in a form suitable for insurance administration with each prescription dispensed. Costs of this additional paperwork would have to be recovered by the pharmacist.

Coordinated Systems Design. Maximum efficiency in claims handling would probably be achieved if any automated data processing system designed for use under Medicare would reflect the needs of Medicaid, CHAMPUS, the Veterans Administration, the Public Health Service, and private drug insurance programs. Accordingly, appropriate consideration should be given to the compatability of a Medicare system with the systems used by other organizations.

The need for an overall systems approach has been stressed by William R. Larson, who has contended that the "major element lacking thus far in dealing with the special health problems of the aged seems to be the failure to develop an overall systems aproach to health information." He outlined the broad implications for an adequate information base as follows:[2]

> "By providing health data on a broad, community-wide scale, and using computer data storage techniques, such a system could allow physicians to get a far greater exposure to vital information on physiological, psychological, and social characteristics. By the use of an educational system controlled by the data bank computers, physicians could participate in a learning experience. Community and public health organizations and personnel would have direct access to computer-based health information systems, allowing them to better plan for their involvement with those needing services."

The use of an integrated, sophisticated systems approach for meeting the requirements of various agencies is implied in several of the recommendations submitted by the U.S. Senate Committee on Government Operations in its study of interagency drug coordination. The Committee noted the need for (1) modernized files on drug information established on a flexible "building block" basis, (2) electronically stored and retrieved patient records in the three Federal hospital systems, and (3) "maximum use of patient records for all Federal programs—research, regulation, purchase of supplies, education and clinical improvement."[3]

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[a] For a description of a successful project of this nature, see Seibert, Stanley; Brunjes, Shannon; Soutter, John C.; and Maronde, Robert F.: "Utilization of Computer Equipment and Techniques in Prescription Processing," Drug Intelligence 1:342–350 (November, 1967).

[2] U.S. Senate, Subcommittee on Health of the Elderly, Special Committee on Aging: "Costs and Delivery of Health Services to Older Americans," U.S. Government Printing Office, Washington, D.C., 1967, Part 1, p. 276.

In addition, in overall systems design, consideration should be given to compatibility with any systems used in drug recall and poison control programs.

Certainly, it would appear that any system developed to handle drug claims should be able to forward data to more than one central computer. This flexibility seems to be mandatory if a multiplicity of governmental and nongovernmental drug programs are to have the cooperation of community pharmacists.[4] Just as the pharmacist cannot practically use 12 telephones each connected exclusively to one of 12 physicians' offices, it would not be feasible for him to have a separate terminal for every drug insurance program that may exist. It seems evident that the use of a single, sophisticated, fully compatible system would contribute to lower administrative costs for most or all of the potential users of the system.

Data Requirements

The decision on which kinds of administrative data are required for a drug program will depend upon the exact nature of the program as established by legislation and regulations.

Under virtually any approach, certain items would probably be needed on each prescription claim.

Drug Identification. Identification of the drug product would be essential in any reimbursement system that is highly automated or that depends on some measure of reasonable charges or costs. This identification would be facilitated by use of the *National Drug Code Directory*, which is scheduled for publication during the spring of 1969. The *Directory* will list essentially all prescription drug products, together with selected over-the-counter items, and will identify each with a nine-digit code.[a] The first three characters will identify the final labeler (who in most cases will be the manufacturer), the next four will identify the particular drug product, and the last two characters will designate the package size in which the vendor purchased the product (and thus will help indicate the quantity discount). If the last item is not necessary for purposes of reimbursement, it can be disregarded. Pharmacist reference to the code would be aided if all manufacturers print the relevant code number in a standard position on the label of each container.

Under a vendor reporting system, the vendor could be expected to report the standard code numbers; under a beneficiary reporting system, however, the general lack of knowledge of drug terminology would probably preclude encoding by the patient, and the administrator would thus be required to undertake costly manual coding.

Quantity Dispensed. Since drug price is determined by both the product and the amount prescribed, the latter would be needed to establish a basis for reimbursement.

Vendor Identification. The vendor could be designated easily by a code number. The vendor code could be used as an index to a master file which would contain addresses and other data needed for disbursement and other administrative purposes.

Patient Identification. Since the patient could also be identified easily by a code number, there would be no need to process data in addition to the number on his identification card. If more than one drug program should be handled through the same system, patient identification would need to be supplemented with an additional item to specify which program assumed liability. Associated with patient eligibility determination are a number of other problems; these are discussed below.

Dispensing Date. This would be needed to satisfy the usual administrative responsibilities related to verification of service.

Prescriber Identification. A code number could be used to identify each physician or other prescriber who might be expected to originate a prescription order for eventual submission to the drug program. Additional data on these prescribers—such as type of practice, training, and the like—could be stored in a central file so that the claims transmittal would not be encumbered by data that could be obtained more efficiently. Such information would be needed particularly in utilization review studies.

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[3] U.S. Senate, Committee on Governmental Operations, Subcommittee on Reorganization and International Organizations: "Interagency Drug Coordination," U.S. Government Printing Office, Washington, D.C., 1966, p. 6.

[4] Woods, William E.: "A Computer Terminal May Be Solution to Pharmacists' Recordkeeping Chores," National Association of Retail Druggists Journal 89: 14–15 (March 20, 1967).

[a] See p. 52.

Patient's Medical Condition. Legislation may limit coverage to drugs needed for certain specified diseases or conditions, and such information would clearly be needed for utilization review. A one- to three-digit code could be designed to permit the physician to indicate on the prescription form either (1) diagnosis, (2) intended therapeutic effect, or (3) simple indication of patient condition. Further research is needed to establish which approach is likely to be most meaningful.

Duration of Drug Supply. Data on prescription duration—that is, the number of days' supply—may be required under legislation, and would enhance utilization control and review. Although the vendor might be requested to indicate the date on which the contents of the prescription would be exhausted, it would probably be more efficient to indicate the supply in number of days (5 days, 100 days, etc.) as indicated by the prescription. Under such conditions, the central computer could calculate the interval during which another prescription for the same drug would not be expected to be received as a claim against the program. Alternatively, dosage instructions might be codified and quantified, and computer determinations made of the intended duration of supply.

Legislative requirements or overall administrative effectiveness may also require submission of data on some or all of the following items for the government to discharge its total program responsibilities:

Refill Status. If the program does not cover refills, this item could be omitted. If refills are covered, two alternative data requirements are possible: (1) the pharmacist could be supplied with a code to designate the refill status, or (2) refill information could be omitted as a claims requirement and instead checks on abuse carried out by means of vendor audit.

Date of Prescription Origination. The program may include an effort to control the procurement of unneeded drugs by stipulating that prescriptions will not be covered when the order originated more than a certain number of days before the patient sought to obtain the product. Rules of this nature could be enforced either (1) by requiring that the date of origination be furnished as part of the claims data, or (2) through regulations concerning vendor dispensing. If the latter alternative were followed, the auditing of pharmacies would be more complex.

Drug Price. Should a drug program rely upon actual market prices, "reasonable" charges, "usual and customary" charges, or similar concepts, the vendor would have to furnish price data on each prescription for the administrator to process the claim.

If, on the other hand, reimbursement were based on factors for product cost plus dispensing expense, it would be possible to design the system so that the vendor would not have to supply any price information on individual claims. Under such approaches, the program administrator could determine product cost by (1) referring to the package size code which would be furnished as a portion of the product identification number, (2) collecting drug price information from various sources, and (3) calculating the reimbursement amount by relating these data. Payments due for dispensing or overhead expense could be established for vendor categories, with appropriate consideration of such factors as geographic area, size of community, and average daily prescription volume. Periodic surveys of pharmacy operations would be needed to collect the basic cost data for the different categories.

Prescription Number. In order to meet the recordkeeping requirements established by State laws, each pharmacist in the United States numbers all dispensed original prescriptions in consecutive sequence. Most drug programs consequently utilize this number as an integral part of the claim record. Since the insurance mechanism would always identify date of service, patient, drug product, drug quantity, etc., it may not be necessary to have the full prescription number—usually involving six or more digits—transmitted as a part of the claims data. Both the vendor and the drug program would benefit if a way could be found to bypass or reduce the size of this informational item.

In order to control the internal processing of claims cost, insurance carriers assign a unique number to each claim received. Under drug insurance, such a number could be generated by combining the vendor identification code with the prescription number, but this would require transmittal of the prescription number. Instead, it would be possible to develop a unique claim number by the central computer on a dated, sequential basis, without regard to the number assigned by the pharmacist. The relative advantages and disadvantages of this approach, especially in relation to effective auditing and utilization review, are in need of further study.

Telephone Order. Because of the possible need for administrative controls on prescriptions ordered by telephone, it may be appropriate to require indication of such orders on drug claims. On the other hand, it may be possible to review such information during field audits.

Other Items. Many drug programs require the pharmacist to furnish special detailed data when a compounded product is dispensed. Since compounding of a prescription order at the pharmacy accounts for only about 2 percent of all prescriptions, it may be possible to define many such special items in the *National Drug Code Directory* and assign them a unique code number. Such standardizing of the identification of compounded drugs would save a considerable amount of time for the vendor. In any instances in which such a simplification proved to be impractical, the normal details concerning ingredients and perhaps their price would have to be submitted manually for claims purposes, but these would be expected to be relatively infrequent.

Identification of the individual actually filling the prescription would be a valuable addition to the claims record. To the extent that assistants are used to aid the professional pharmacist, the need for such data would probably increase.

Also useful would be information to indicate whether the prescription was dispensed directly to the patient, to the patient's agent, to the patient via the vendor's own delivery service, via postal service, and the like.

Where the use of electronic terminals becomes an important means of claims transmission, a method will have to be found to demonstrate that the patient actually received the drug. Current procedures simply require him to sign the claim form. Since the pharmacist keeps the original prescription order on file, it is likely that the patient—or his agent—could sign the order to signify that a bonafide insurance claim had been created. Verification could be a function of the auditors.

Summary of Data Requirements. A tentative summary of the data requirements which would be involved in the use of one kind of electronic terminal is illustrated below. Included are *identification entries* that would be introduced into the terminal by the use of identification cards (perhaps similar to those now used as gasoline, bank, or department store credit cards) together with *essential keyboard entries* that would be required for almost any drug insurance program. Also shown are *elective keyboard entries* that might or might not be required, depending on the program legislation and regulations. For the keyboard entries, the number of X's indicates the number of characters—numbers, letters, or both—which presumably would be concerned.

Data Requirement Summary

Card Entries

- Vendor Identification [a]
- Patient Identification
- Physician Identification
- Drug Identification

	Essential Keyboard Entries
XXX	Reason for taking drug (code)
XXX	Quantity dispensed
XXX	Duration of drug supply
XX	Date dispensed [b]

	Elective Keyboard Entries [c]
X	Refill status
XX	Date prescription originated
XXXX	Drug price
XXXXXX	Prescription number
X	Telephone order

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[a] Identification of the vendor could be built into the terminal.

[b] Three alternatives are possible: (1) if the station were polled at the close of each business day, this item could be omitted; (2) day of the week could be indicated by a one-character code, or day of the month by a two-character code; (3) a special unit to record the date could be built into the terminal, with the vendor required to set this unit at the start of each business day.

[c] As may be required by program legislation or regulations.

In addition to the foregoing, the program administrator would be expected to record and be able to retrieve such data as (1) date of claim receipt, (2) date of claim payment, (3) amount of payment, (4) basic statistics on program participants—prescribers, vendors, and beneficiaries—and (5) any additional information required under the actual legislative features of the program.

Program Regulations

In a number of existing domestic and foreign drug programs,[5] it has been found desirable or essential to establish regulations aimed at reducing program costs or improving program administration. In designing a drug insurance program under Medicare, these—and other possible alternatives—deserve consideration.

Amount of Drug Supplied. In order to control various problems that may arise under a prescription drug program, the amount of the drug supplied—whether for acute or chronic illness—may be restricted by regulations. At least five possible alternatives may be discussed.

The program could stipulate no restrictions on quantity, and provide reimbursement for any amount of the drug supplied. Such an approach would presumably be endorsed by most prescribers, vendors and beneficiaries. The experience of State Medicaid drug programs, however, suggests that unrestrictive drug prescribing without effective peer review leads to excessive quantities of prescribed drugs and to increasing program costs which may not be justified by clinical needs.

The program could allow the quantity to be determined at the discretion of the patient, thus allowing him to purchase smaller amounts than the prescribed quantity (presumably conserving his own funds) or to purchase larger than the prescribed amount (presumably to take advantage of a possible quantity discount). Aside from the obvious clinical hazards in such an approach, and the equally obvious incentives to fraud, this method is prohibited by Federal and State laws. These laws allow the patient to decide only to purchase or not to purchase the drug in the quantity ordered by his physician.

Some programs refuse to pay for a drug supply (except for some maintenance drugs) that exceeds a limit of 5, 12, 34 or other fixed number of days. This maximum-amount restriction has apparently been instituted to prevent excessive use, and to restrain beneficiaries who might be inclined to share the drug benefits with ineligible persons. It should also be recognized, however, that this approach neglects the medical and economic needs of those patients who should receive a supply of drugs larger than that allowed by some arbitrary regulation. A more logical alternative would be controlling patient abuse as a function of the claims processing method, with the computer used to calculate when the drug supply is likely to be exhausted and to identify deviant cases for investigation.

Instead of limiting the drug supply to a maximum amount, regulations could be established to encourage physicians to write prescriptions for large amounts—such as for a 90-day supply or more. Such a minimum-amount restriction would be inconsistent with (1) the need for patient adjustment to the most effective dosage form and strength when certain drugs are given, (2) the need to change medications because of adverse drug reaction, (3) the use of a limited drug supply to induce a patient to return to his physician for re-evaluation of his medical condition, and (4) the possibility that the drug may deteriorate after a relatively short time. In addition, this minimum-amount restriction would aggravate the problem of drug wastage.

It appears that neither an arbitrary maximum-amount restriction nor a minimum-amount restriction could be expected to achieve the best results in improving health care at minimum cost. The variables concerning the different beneficiaries involved, the types of drugs prescribed, and the nature of the illnesses under treatment are so numerous and complex that no single administrative regulation would be justified. For example, it might be arbitrarily decided that such drugs as digitalis, thyroid and tolbutamide could be dispensed for any patients in amounts appropriate for 90 days of treatment or more, and—on equally arbitrary grounds—that such drugs as prednisone, secobarbital and tetracycline could be dispensed for no more than a 30-day period. Because of the many variables involved, however, such an approach with either a single maximum or a single minimum amount could well lead to serious difficulties. Further study would obviously be required to establish any regulations or guidelines concerning quantities for covered drugs.

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[5] "Current American and Foreign Programs," *op. cit., passim.*

Instead, it seems that only an organized, systematic professional peer review—based upon solid statistical data, and including analyses of reports on the medical condition of individual patients—would be most likely to be meaningful in any evaluation of drug quantity problems. Such an approach would permit a variety of solutions to be used at different levels to deal with specific problems that may arise. It would permit appropriate assignment of responsibilities to the physician, the vendor, and the patient, respectively, as may be required.

Time Lapse After Origination of Prescription. In an effort to minimize the dispensing of prescriptions which are no longer needed by a patient, some programs provide that (1) drugs for acute conditions are not eligible for reimbursement if the original prescription order was filled more than three days after the prescription was written, and (2) drugs for chronic conditions are ineligible if the prescription order was presented more than seven days after origination. Other programs impose limitations of up to 10 days, regardless of whether the drug is for an acute or a chronic illness.

These approaches deserve further study.[a]

Refills and Renewals. A prudent policy on refills and renewals can influence both the quality of patient care and the cost of a drug program. One physician, for example, has noted that unneeded renewals under State welfare drug programs are "a major part of the excess cost problem." [6] Another aspect of the problem has been described as follows:

> ". . . Many patients are required to return for unnecessary physician visits merely to have prescriptions renewed that, had they been cared for in the private sector, would have been attended to without the need for returning to see a physician. Not only is this a costly procedure in that a physician fee is developed by the return visit, but also there is a very significant factor in emphasis as regards the health of the patient; either we make the patient independent and therefore health conscious regardless of what disease he has or we develop a system that causes dependency and disease orientation on his part." [7]

Still another aspect of the problem concerns the role of pharmacists, many of whom apparently prefer a "no refill" policy since this would free them from the obligation of discussing with patients why the number of refills had been restricted by the physician. Yet where restrictions have been placed on "refills" by State drug programs, it is believed that pharmacists often bypass such regulations by means of "renewals."

At least four program alternatives seem possible:

1. Disregard the problem and let current practice prevail.
2. Establish a policy of no refills and no renewals.
3. Require that every prescription eligible for insurance coverage must carry an indication from the physician concerning the number of authorized refills, if any. Further, the program could take the position of refusing to pay for refills when the original order had been too long before—for example, 90 or 180 days. Once the time limit had passed, the patient would need to be re-examined by the physician before a renewal of the prescription could be issued. Different time periods might be established for chronic and acute conditions.
4. A fourth alternative might rely upon approach (3) above, coupled with referral of any problems to a utilization review committee. Profiles and standards could be developed on drug classification, the use of specific drugs, and similar factors, and studies could then be conducted to develop refill and renewal policies best suited to yield maximum health care at the lowest practical cost.

Prescription Blanks. In designing a Medicare drug program, special attention must be directed to several problems concerning prescription blanks.

One aspect was discussed in a recent report:

"Furnishing signed prescription pads to

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[a] For one analysis of the drug wastage problem, see "A Fortune Wasted on Never Taking Drugs," Medical News 166:4 (Dec. 10, 1965).

[6] Montgomery, Burtis E.: "Drugs: The Medical Care Program's Biggest Headache," Illinois Medical Journal 128:614 (Dec. 1965).

[7] Breslow, Irwin H.: "Notes on a Medical Utilization Review Procedure Under a Drug Insurance Program." A paper especially prepared for the Social Security Administration, Oct. 9, 1967, p. 8.

> drugstores constitutes 'unprofessional conduct,' the Connecticut State Medical Society warns members, and could lead to suspension of a doctor's license. Several physicians who supplied the signed pads to pharmacists, reports the society, defended their action on the ground that it saved time with telephoned prescriptions and in welfare cases where duplicate forms are required. The Connecticut society's stand was backed by an AMA spokesman. There can be no justification for pre-signed prescription blanks, says the AMA, because of the danger of their misuse."[8]

Still another problem arises from the practice of pharmacists who furnish pre-printed prescription forms free of charge to physicians. Because of the potential abuse of this advertising scheme, it would seem that any insurance program might well disallow prescriptions written on such forms.

The latter difficulty—and others—could be resolved if the administrator for a Medicare drug insurance program (or other organization) pre-printed standard prescription forms, supplied them free of charge to physicians and other prescribers, and then required their use for program beneficiaries. It is possible that a well-designed form, meeting the requirements of essentially all government and private drug insurance plans, could be voluntarily adopted and used by physicians for all their patients.

Such a form could, by the use of appropriate check-off boxes, enable the physician to authorize the pharmacist to dispense a low-cost, high-quality, generic-name drug in place of any more costly brand-name drug that was actually prescribed. Such authorization is widely used by some governmental drug insurance programs and by many hospitals.[9-10]

Vendor Agreements. If substantial reliance were to be placed on drug vendors in the processing of drug benefit claims and in reimbursement, it is contemplated that vendors—like the providers of service under the present Medicare law—would be able to participate in the drug program only if they entered into an agreement to do so with the Secretary of Health, Education and Welfare. They would have to agree (1) to accept certain limits on the amounts they would charge program beneficiaries, (2) to submit bills with such frequency and in such form as may be specified, (3) to make available drug and prescription records for drug audits, (4) to keep such checks on the accuracy of the dispensing of prescriptions as may be provided under regulations, and (5) to meet such other conditions of health and safety as may be provided in regulations.

As drug vendors under such a program, it would seem feasible to include community, mail-order and hospital outpatient pharmacies, clinics, those extended care facilities which desired to act as drug vendors, and, in certain cases, dispensing physicians.

Physicians could be permitted to act as drug vendors in the program only under certain conditions established by the Secretary. In determining reimbursement of such a dispensing physician, consideration would be given among other factors to the extent of any other professional services he performed at the time he dispensed the drug, and of any charges he made for those services; that is, the physician would not be reimbursed both for a dispensing charge as part of his "reasonable charges" as defined in the present Medicare law for professional services, and also for a dispensing allowance in his capacity as a drug vendor. Any dispensing physician participating in the drug program would be required, like any other vendor, to make available his records for drug audits.

Use of Nongovernmental Carriers. If a new drug benefit is added to the Medicare program, administrative responsibility would presumably rest with the Secretary of Health, Education, and Welfare, with a primary delegation of authority to the Social Security Administration. As the legislative specifications develop for the new program, and as the many complex problems of designing the most feasible administrative methods are resolved, it may prove desirable to enlist the assistance of private insurance groups or other nongovernmental organizations to serve as regional or nationwide carriers.

The possible use of such organizations and their specific functions would depend to a large extent on the resolution of other important administrative questions. For example, the nature of the automated data processing system used in administering the drug benefit would have an important bearing on the delegation of functions to outside organizations. Also important would be the experience and proficiency developed by various nongovernmental organizations in administering drug-benefit claims.

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[8] Medical World News 8:81 (September 22, 1967).

[9] "Current American and Foreign Programs," *op. cit., passim.*

[10] Task Force on Prescription Drugs: "The Drug Prescribers," U.S. Government Printing Office, Washington, D.C., 1968, p. 48.

Relation to Other Drug Programs

In designing a Medicare drug program, major consideration would need to be given to its relation to other drug insurance programs, and to other activities involving drug use.

As noted above,[a] an automated claims processing system for Medicare should be developed so that it would be compatible with systems used by other drug programs, including those of Medicaid and other Federal programs, and perhaps those developed for nongovernmental programs.

In addition, it would be beneficial to develop consistent administrative regulations wherever feasible. In this respect, coordination of Medicare and Medicaid programs would be particularly important, both to minimize costs and to aid participants in understanding their respective benefits and responsibilities. Major factors calling for study in such Medicare-Medicaid coordination would include (1) use of the same or similar automated data processing system, (2) use of a uniform reporting system and standardized language, (3) use of the same or similar methods for determining and communicating participant eligibility, (4) use of the same regulations on refills, quantities of drugs supplied, etc., (5) use of the same formula for vendor reimbursement, (6) use of the same or similar approaches for utilization review, (7) use of coordinated field audits, and (8) use of the same formulary.

It is possible that other drug insurance programs—such as those of private insurance companies—might use compatible data processing systems, but it does not seem likely that they would necessarily utilize administrative regulations similar to those for government programs.

Another value of a Medicare drug insurance program, especially if it included a highly sophisticated automated claims processing system, would be its use to attain goals not directly related to drug insurance. Among such applications are these.

- With the utilization of a special computer, the systems network for forwarding drug claims could be used to transmit reports on adverse drug reactions.
- The system could likewise be used to facilitate drug recalls.[b] The coding identification base would help in tracing products that must be returned to the manufacturer, while the insurance mechanism—taking advantage of the same code—would help identify the products and pinpoint the locations where they have been dispensed. With an appropriate system, drug recall information could be sent very quickly to practically every vendor in the United States, or to those in any specific area in which the products in question were thought to have reached the retail level.
- The Medicare data processing system could fill a role in implementing poison control operations. Further studies are needed.
- Additional studies are required to determine how the data processing system could be utilized as part of inventory control operations for drugstores and other vendors.
- One of the most valuable dividends of the program would be the information obtained on drug prescribing in relation to the social and health characteristics of the elderly. This information, available from statistics generated through the program, could have significant value to physicians and health planners in developing future programs of health care.

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[a] See p. 42.

[b] Several aspects of this problem are outlined in the Journal of the American Pharmaceutical Association 7: 569–590 (Nov. 1967).

CHAPTER 7

CLASSIFICATION AND CODING

A classification and identification scheme is an integral part of any common language developed for describing pharmaceutical preparations, devices and other medical supplies prescribed for recipients of medical care.

The need for such a common language—especially a machine-readable language—has been clearly recognized:

> "Use of a common language will facilitate the development of compatible systems for the rapid and total exchange of drug information by telephone, television, phototelegraphy, or other rapid electronic means both nationally and internationally."[1]

Wherever the cost of prescription drugs is to be covered for outpatients under any governmental or other insurance program, the necessity for consensus on classification, coding and identification of drug products is apparent. A common system of communicating the minimum basic information on pharmaceutical preparations is essential in the interests of both rational drug utilization and program economy.

If prescription drug benefits are to cover all welfare beneficiaries in the 50 States, and all outpatient beneficiaries under Medicare, a minimum of 300 million prescriptions could be involved each year. The administrative and accounting costs for processing such a mass of prescriptions without a universal coding, classification and identification system would inflate total program costs beyond acceptable limits.

Classification

To find methods of coping with this problem, the Task Force staff appointed an *ad hoc* joint committee on classification and coding which began a series of meetings in July 1967. Appointees to this committee included representatives of the American Medical Association, the National Library of Medicine, the United States Pharmacopeia, the National Formulary, the Food and Drug Administration, the American Society of Hospital Pharmacists, the Drug Information Association, the National Pharmaceutical Council, and the Pharmaceutical Manufacturers Association, as well as various universities and State agencies.

A subcommittee on classification was asked to develop criteria for classifying drugs in order to create a system whereby pharmaceutical preparations could be identified, and desired data stored and retrieved by means of existing and planned electronic data processing techniques and equipment.

During the course of the many committee and subcommittee meetings, other experts from various fields were invited to sit with the Task Force committee. This multi-disciplinary group evaluated all of the major classification schemes currently in use by professional and trade associations, Federal and State governments, and various proprietary organizations. All of these involved what were considered to be undesirable characteristics, such as the indiscriminate and excessive use of "miscellaneous" categories.

Based on a desire to relate cost analysis and utilization studies to "how" and "why" drugs and other products are being used, the new classification scheme was designed to accommodate products by categories reflecting their actual therapeutic intent. This version places drugs in multiple settings, and permits final data collection reflecting these settings and providing cost breakdowns according to actual drug usage.

The final proposed classification—the result of eight revisions—contains 26 major headings and various subheadings as recommended by the classification committee. In addition, each major heading carries a definition to clarify further the intended content of a specific category.

The major headings are as follows (the complete list of headings and subheadings, and the respective definitions, are presented at the end of this chapter):

AA Antiallergics
A Anti-infectives
AD Antidotes, deterrents and poison control agents
CA Antineoplastics

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[1] Martin, Eric W.: Presidential Address, Drug Information Association, Washington, D.C., October 9, 1965.

AU	Autonomics
CV	Cardiovascular drugs
N	Central and peripheral nervous system drugs
DN	Dental and oral drugs
DE	Dermatologics
DP	Devices, prosthetics and other medical supplies
DG	Diagnostics
ET	Ear, nose and throat drugs
EN	Enzymes and coenzymes
GA	Gastrointestinal drugs
GE	Genital system drugs
HE	Hematics
HM	Hormones, synthetic substitutes and antagonists
MM	Immunologicals
M	Metabolics, electrolytes, calorics and nutrients
MU	Musculoskeletal drugs
TH	Ophthalmics
PA	Pharmaceutic aids
PY	Psychopharmacologics
RA	Radiopharmaceuticals, radiation sensitizers and protectives
RE	Respiratory drugs
UR	Urinary system drugs

In developing the classification, an effort was made to utilize mainly headings and major subheadings—that is, to keep the classification in the first and second levels of hierarchy. In only a few instances was it necessary to extend into the third level to accommodate a particular category. This enables a variety of users of the system to subdivide further as their needs dictate, but the common point of reference would always be retained at the second or third hierarchical level. Examples of the first and second level classification, and of the first through the third, respectively, are the following:

First level	CV	Cardiovascular drugs
Second level	CV1	Antiarrhythmics
	CV2	Antihypertensives
	Etc.	

First level	A	Anti-infectives
Second level	A1	Antibacterials
Third level	A1A	General antibacterials
	A1B	Leprostatics
	A1C	Tuberculostatics
	Etc.	

In none of the 26 categories was it necessary to use a "miscellaneous" heading at any level. This bears out the belief of the subcommittee that each drug product is applied with a specific therapeutic intent and must be classified accordingly. From the standpoint of statistical and reporting requirements, it apears essential that no product be buried—by default or design—under a "miscellaneous" heading.

Approximately 1,000 copies of the seventh revision were circulated among user groups representing a cross section of State and Federal agencies, professional and trade organizations, and private individuals. Changes proposed in the seventh revision have been incorporated in the eighth revision which is presented here, and which has also been distributed for further field tests in several nongovernmental and Federal programs. After the completion of these extensive field trials in various settings, recommended changes will be evaluated by the classification committee, and necessary modifications made in the ninth and presumably final revision. It is anticipated, however, that the present eighth revision will be acceptable for use in the Title XIX program as well as in other Federally-sponsored programs where classification and identification of drug products is necessary.

Coding

Surveys by the Task Force *ad hoc* committee on drug coding clearly revealed the need of various drug programs—State vendor drug programs and others—for a common drug code for use in the reporting, payment, and review of vendor drug claims by means of electronic data processing equipment. A similar need was expressed by major drug producers and wholesalers.

In general, it appeared, all the groups involved in these programs required three items of drug product information—manufacturer; drug name, dosage form and strength; and package size. Although additional refinements and requirements were indicated, it was widely agreed that such additional information should probably be retrievable from a central information file supplied and used by the organization requiring the data.

To design a system that would accommodate the needs of most or all potential users, the committee studied several approaches. Of particular importance was the problem of a "short code" versus a "long code."

- The need for a short product code number was stressed by pharmacy administrators of the

State Medicaid programs that handled the bulk of Medicaid prescriptions throughout the Nation. Most of such States were using a four- or five-digit configuration in their computer operations. Imposition of a requirement for additional digits in these systems would necessitate complete reformation of all their computer programs, at considerable expense to the States and the Federal Government.

- On the other hand, use of a short or random number (sometimes known as an "idiot number") as a computer identification would be valueless to those organizations that had no computer capability.
- Finally, some organizations—notably manufacturing and distributing groups—expressed a need for a longer number, with at least nine digits, to provide for adequate product identification and to be compatible with existing systems.

In November 1968, agreement was finally reached on a nine-digit code as the basis of the proposed coding system. The concensus was achieved among members of the National Drug Trade Conference, the Pharmaceutical Manufacturers Association, the National Wholesale Druggists Association, the Task Force, and the representatives of various State vendor drug programs. In order to assist in the prompt development and implementation of the new National Drug Code, the various manufacturers and trade groups—either individually or collectively—have offered technical assistance to those States currently administering or developing a Title XIX program.

Basis of the system is a 3–4–2 drug code format to provide the three major items of identification.

Manufacturer. The first three digits will be used to identify the final labeler of the product. In most cases, the labeler will also be the product manufacturer. For purposes of product identification in an effective drug recall system, however, the code must indicate the name of the labeler. The prime manufacturer of a product repackaged and labeled by another company must be identified by batch and lot number.

The three-digit labeler or manufacturer number will be assigned by the Food and Drug Administration.

Drug Product. As many as four characters may be used to identify product name, dosage form and strength. The labeler or manufacturer may select this portion of the code.

A drug will have the same identification number whether listed under its brand name, or under its generic name and the name of the manufacturer.

Package Size. Two numeric characters will serve to identify all package sizes of a particular dosage form and strength as marketed by each manufacturer. The two-digit code will be assigned by the manufacturer. Future plans call for a coordinated industry-wide effort to develop a standardized package code. Officials of the Pharmaceutical Manufacturers Association have pointed out the complexities of developing such a code, but have expressed a desire to cooperate with the Federal Government in resolving the problem.

The format of the drug code may be shown as follows:

9	9	9

0	H	2	6

1	4

(It will be noted that when an identification number occupies less than the total of allotted spaces, it is always right-justified, and the appropriate number of leading zeros is inserted.)

The National Drug Code number would appear in a designated position on the label in this form:

999–H26–14

It would be interpreted as follows:

999—John Doe and Sons
H26—Xerocillin, 50-mg. tablets
14—bottle of 100

In the case of future products, it is presumed that drug identification numbers will be assigned at the time a New Drug Application is approved.

The nine-digit code, with appropriate use of numbers and letters in combination, would enable as many as 27,000 manufacturers to identify some 800,000 different products apiece.

Since the drug identifying number would be necessary in computerized processing of vendor drug claims, it has been suggested that FDA product registration and the development of a computer-based product identification number be specified as requirements for inclusion of any product as a covered drug in any public assistance drug program.[2]

It has likewise been suggested that implementation of the National Drug Code system would make it desirable or necessary for drug manufacturers to review and renumber their master formulas, submitting new product identification code numbers to avoid confusion, and to review and in some cases modify their quality control and production work sheet forms, their batch number practices, their recordkeeping methods, and their protocol procedures. At the same time, procedures for raw materials procurement, inventory, and other recordkeeping methods would need review and revision.[3]

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[2] Jeffries, Seymour B.: "GMP, One Solution is the Computer," Drug and Cosmetic Industry 103 (No. 3): 56 (Sept. 1968).

Drug wholesalers have suggested that the identifying code number will eventually be used in all ordering, assembling, inventory management, and billing of all drugs.

Product labels would need to be redesigned to include the identifying code number so that the dispensing pharmacist would need look only to the label for the number he must have for all Medicare or Medicaid billing purposes.

Finally, drug makers would have to set up appropriate procedures for handling and transmitting substantive changes in labeling information and new code number assignments so that the FDA product data file will be kept up-to-date.

Unit Dose Identification

The inability to obtain rapid identification of individual tablets or capsules in unlabeled drug containers—or carried loose in an envelope or pocketbook—has been a matter of serious concern to physicians attempting to learn which medications their new patients may have been taking. It has been even more serious in coping with accidental poisonings or attempted suicide.

Widespread use of the proposed National Drug Code described above could have significant value in such cases if the code number were required to appear not only on both the commercial package label as distributed to vendors and on the prescription label as distributed to patients, but also on each capsule and tablet. A number of manufacturers are already imprinting a numbered code on their capsules and other finished unit dosage products, and others have announced their intention to follow suit.

National and International Systems

The proposed new classification and identification systems could well be used in an international adverse drug reaction reporting system. The Chemical Abstract Service number currently assigned to all foreign drug entities could be added to the central computer file, and used as the reference point in correlating all national and international data on adverse reactions.

To implement such an application, the Task Force staff has been meeting with representatives of the Canadian Government and of the World Health Organization to coordinate coding and classification efforts. Procedures are being developed to identify the country of origin of drug products, especially when these products are carried in unlabeled containers.

The new classification and coding systems could likewise play a valuable role in improving drug utilization review studies.[a] Now, with the lack of a common language, most of the reporting agencies—Federal and State programs and private insurance company operations—employ different identification and classification schemes, and consequently produce drug use and drug cost data that are not readily comparable or meaningful outside of the originating agency.

Drug Code Directory

As pointed out above,[b] the effective, rapid and accurate processing of drug claims data requires that vendors and program administrators be able to refer to a single, comprehensive nomenclature and coding system for identifying drug products covered by present and anticipated programs.

Because all basic product information concerning new drugs entering the market—and changes in existing formulations—is collected, processed and regulated by the Food and Drug Administration, this agency was assigned the task of developing a National Drug Code Directory, along with a data bank for storage and retrieval of label information on every product on the market.

A preliminary version of such a directory has been produced for examination and field testing.[4] In later versions, it is expected that the new National Drug Code number will be incorporated.

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[3] *Ibid.*

[a] See Chapter 8.

[b] See p. 50.

As the code numbers appear on the labels of all drug products, and in company catalogs and standard reference sources, it may eventually be possible for the government to discontinue wide distribution of the directory, while still maintaining the data bank.

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[4] "National Drug Code Directory (Prototype Issue)," Science Information Facility, Food and Drug Administration, Washington, D.C., April 1968.

Proposed Task Force Drug Classification System

- AA Antiallergics
  - AA1 Allergenic Extracts, Desensitizing
  - AA2 Antihistaminics
  - AA3 Immunosuppressives, Transplant Therapy
- A Anti-Infectives
  - A1 Antibacterials
    - A1A General Antibacterials
    - A1B Leprostatics
    - A1C Tuberculostatics
  - A2 Antifungals
  - A3 Antimetazoals
    - A3A Anthelmintics
    - A3B Antiarthropods
    - A3C Hirudicides
  - A4 Antiprotozoals
    - A4A Amebicides
    - A4B Balantidicides
    - A4C Leishmanicides
    - A4D Plasmodicides
    - A4E Toxoplasmacides
    - A4F Trichomonacides
    - A4G Trypanosomicides
  - A5 Antirickettsials
  - A6 Antivirals
  - A7 Spirocheticides
  - A8 Topical Antiseptics and Germicides
- AD Antidotes, Deterrents and Poison Control Agents
  - AD1 Adsorbents for Poisons
  - AD2 Alcohol Deterrents
  - AD3 Anticoagulant Antagonists
  - AD4 Antifolate Antagonists
  - AD5 Antivenins
  - AD6 Cholinesterase Inhibitor Antagonists
  - AD7 Cyanide Antidotes
  - AD8 Dialysis Solutions
  - AD9 Emetics
  - ADA Gastric Lavages
  - ADB Heavy Metal Antidotes
  - ADC Narcotic Antagonists
  - ADD Penicillin Antidotes
  - ADE Phosphorus Antidotes
  - ADF Smoking Deterrents
- CA Antineoplastics
  - CA1 Alkylating Agents
  - CA2 Antimetabolites
  - CA3 Anticancer Alkaloids
- AU Autonomics
  - AU1 Adrenergics
  - AU2 Antiadrenergics
  - AU3 Anticholinergics
  - AU4 Cholinergics
- CV Cardiovascular Drugs
  - CV1 Antiarrhythmics
  - CV2 Antihypertensives
  - CV3 Capillary Fragility Agents
  - CV4 Cardiotonics
  - CV5 Sclerosing Solutions
  - CV6 Vasoconstrictors
  - CV7 Vasodilators
  - CV8 Vasopressors
- N Central and Peripheral Nervous System Drugs
  - N1 Analeptics
  - N2 Analgesics and Antipyretics
  - N3 Anesthetics
    - N3A General
    - N3B Local
  - N4 Anticonvulsants
  - N5 Antiparkinsonian Drugs
  - N6 Sedatives and Hypnotics
- DN Dental and Oral Drugs
  - DN1 Anti-infectives, Dental
  - DN2 Cariostatics
  - DN3 Dental Protectants
  - DN4 Dentrifrices
  - DN5 Denture Adhesives
  - DN6 Mouthwashes
- DE Dermatologics
  - DE1 Abrasives
  - DE2 Anti-infectives, Dermatologic
  - DE3 Anti-inflammatories, Topical
  - DE4 Antipruritics
  - DE5 Antipsoriatics
  - DE6 Antiseborrheics
  - DE7 Astringents, Dermal
  - DE8 Caustics
  - DE9 Cleansing Agents
  - DEA Deodorants and Antiperspirants
  - DEB Depilatories
  - DEC Escharotics
  - DED Hypoallergenic Cosmetics
  - DEE Keratolytics
  - DEF Keratoplastics
  - DEG Pigmentation Agents

  - DEH Protectives and Maskers
  - DEJ Tissue Proliferants
  - DEK Vesicants
- DP Devices, Prosthetics and Other Medical Supplies
  - DP1 Devices
  - DP2 Medical Supplies
  - DP3 Prosthetics
- DG Diagnostics
  - DG1 Diagnostic Dyes
  - DG2 Diagnostic Skin Testing Preparations
  - DG3 Test Reagents
  - DG4 Pregnancy Tests
  - DG5 Radio-Opaques
  - DG6 Tissue/Organ Function Tests
- ET Ear, Nose and Throat Drugs
  - ET1 Analgesics, ENT
  - ET2 Anti-infectives, ENT
  - ET3 Anti-inflamatory agents, ENT
  - ET4 Astringents, ENT
  - ET5 Ceruminolytics
  - ET6 Decongestants, Nasal
  - ET7 Lubricants, ENT
- EN Enzymes and Coenzymes
  - EN1 Coenzymes
  - EN2 Enzymes
  - EN3 Enzyme Activators
  - EN4 Enzyme Precursors
- GA Gastrointestinal Drugs
  - GA1 Acidifiers, Gastric
  - GA2 Adsorbents
  - GA3 Antacids, Gastric
  - GA4 Antidiarrheals
  - GA5 Antiemetics
  - GA6 Antiflatulents
  - GA7 Anti-infectives, Gastrointestinal
  - GA8 Antispasmodics, Gastrointestinal
  - GA9 Appetite Depressants
  - GAA Appetite Stimulants
  - GAB Cathartics and Evacuants
  - GAC Digestants
  - GAD Flora Modifiers and Replacements
  - GAE Hemorrhoidal Preparations
- GE Genital System Drugs
  - GE1 Antifertility Drugs
  - GE2 Anti-infectives, Urethral and Vaginal Topicals
  - GE3 Fertility Drugs
  - GE4 Lubricants
  - GE5 Oxytocics
  - GE6 Uterine Relaxants
  - GE7 Vaginal Astringents and Cleansers
- HE Hematics
  - HE1 Antianemics
  - HE2 Anticoagulants
  - HE3 Antipolycythemics, Non-Radioactive
  - HE4 Blood Replenishers
  - HE5 Blood Volume Expanders
  - HE6 Hemostatics
- HM Hormones, Synthetic Substitutes and Antagonists
  - HM1 Adrenal Cortex Hormones
  - HM2 Hormone Antagonists
  - HM3 Oral Hypoglycemics
  - HM4 Ovarian Hormones
  - HM5 Pancreatic Hormones
  - HM6 Parathyroid Hormones
  - HM7 Placental Hormones
  - HM8 Pituitary Hormones, Anterior
  - HM9 Testicular Hormones
  - HMA Thyroid Hormones
- MM Immunologicals
  - MM1 Antitoxins
  - MM2 Immune Serums
  - MM3 Toxoids
  - MM4 Vaccines
- M Metabolics, Electrolytes, Caloric and Nutrients
  - M1 Anabolic Drugs
  - M2 Antihyperlipemics
  - M3 Dietary Supplements
    - M3A Carbohydrates
    - M3B Lipids
    - M3C Minerals
    - M3D Proteins
    - M3E Vitamins
  - M4 Dietetic Preparations
    - M4A Salt Substitutes
    - M4B Sugar Substitutes
  - M5 Electrolytes and Fluid Balance Drugs
    - M5A Acidifiers, Systemic
    - M5B Alkalizers, Systemic
    - M5C Electrolyte Removers
    - M5D Fluid and Electrolyte Replenishers
  - M6 Hypouricemics
    - M6A Uricosurics
  - M7 Lipotropics

- MU Musculoskeletal Drugs
  - MU1 Antirheumatics
  - MU2 Bone Preparations
  - MU3 Counterirritants
  - MU4 Skeletal Muscle Relaxants
  - MU5 Skeletal Muscle Stimulants
- TH Ophthalmics
  - TH1 Antiglaucoma Agents
  - TH2 Anti-infectives, Ophthalmic
  - TH3 Anti-inflammatory Agents, Ophthalmic
  - TH4 Astringents, Ophthalmic
  - TH5 Contact Lens Solutions
  - TH6 Eye Washes
  - TH7 Miotics
  - TH8 Mydriatics
- PA Pharmaceutic Aids
  - PA1 Coloring Agents
  - PA2 Diluting Agents
  - PA3 Emulsifying and Suspending Agents
  - PA4 Flavoring Agents
  - PA5 Perfuming Agents
  - PA6 Preserving Agents
  - PA7 Wetting Agents
- PY Psychopharmacologics
  - PY1 Antianxiety Agents
  - PY2 Antidepressants
  - PY3 Antipsychotics
  - PY4 Psychotomimetics
- RA Radiopharmaceuticals, Radiation Sensitizers and Protectives
  - RA1 Antipolycythemics, Radioactive
  - RA2 Radiation Protectants
  - RA3 Radiation Sensitizers
  - RA4 Radiopharmaceuticals
    - RA5 Diagnostic
    - RA6 Therapeutic
- RE Respiratory Drugs
  - RE1 Antitussives
  - RE2 Bronchodilators
  - RE3 Expectorants
  - RE4 Mucolytics
  - RE5 Respiratory Gases
- UR Urinary System Drugs
  - UR1 Analgesics, Urinary System
  - UR2 Antidiuretics
  - UR3 Anti-infectives, Urinary System
  - UR4 Antispasmodics, Urinary System
  - UR5 Diuretics

ANTIALLERGICS

Reduce the magnitude of the hypersensitive state and prevent or alleviate the signs and symptoms of hypersensitivity reactions:

Includes

- Allergenic Extracts, Desensitizing
- Antihistaminics
- Immunosuppressives, Transplant Therapy

Excludes

- Anti-Inflammatory Steroids (See under Hormones, Synthetic Substitutes and Antagonists)
- Radiation Protectants (See under Radiopharmaceuticals, Sensitizers and Protectives)
- Bronchodilators (See under Respiratory Drugs)
- Adrenergics (See under Autonomics)
- Vaccines (See under Immunologicals)
- Anti-infectives, Gastrointestinal (See under Gastrointestinal Drugs)
- Anti-infectives, Urinary (See under Uriary System Drugs)
- Antineoplastic Antibiotics (See under Antineoplastics)
- Preparations specifically formulated for topical application to the skin, eye, ear, nose ,throat, mouth or genital tract (See under Dermatologics, Dental and Oral Drugs, Ear, Nose and Throat Drugs, Genital System Drugs, and Ophthalmics)

ANTIDOTES, DETERRENTS AND POISON CONTROL AGENTS

Antagonize the effects of, or facilitate the removal of, or inhibit exogenous or endogenous intoxicants, or discourage the excessive consumption of alcohol or tobacco.

Includes

- Adsorbents for Poisons
- Alcohol Deterrents
- Anticoagulant Antagonists
- Antifolate Antagonists
- Antivenins
- Cholinesterase Inhibitor Antagonists
- Cyanide Antidotes
- Dialysis Solutions
- Emetics
- Gastric Lavages
- Heavy Metal Antidotes (Chelating Agents)
- Narcotic Antagonists
- Penicillin Antidotes
- Phosphorus Antidotes
- Smoking Deterrents

Excludes

- Barbiturate Antagonists (See under Central and Peripheral Nervous System Drugs)
- Curare Antidotes (See under Musculoskeletal Drugs)
- Hormone Antagonists (See under Hormones, Synthetic Substitutes and Antagonists)

ANTI-INFECTIVES

Prevent or treat local or systemic disease processes caused by pathogenic organisms.

Includes

- Antibacterials
  - General Antibacterials (Antibiotics, Sulfonamides, etc.)
  - Leprostatics
  - Tuberculostatics
- Antifungals
- Antimetazoals
  - Anthelmintics
  - Antiarthropods
  - Hirudicides
- Antiprotozoals
  - Amebicides
  - Balantidicides
  - Leishmanicides
  - Plasmodicides
  - Toxoplasmacides
  - Trichomonacides
  - Trypanosomicides
- Antirickettsials
- Antivirals
- Spirocheticides
- Topical Antiseptics and Germicides

ANTINEOPLASTICS

Inhibit the proliferation or spread of malignant cells.

Includes

- Alkylating agents, antimetabolites, anticancer alkaloids, etc.

Excludes

- Antipolycythemics (See under Hematics)
- Hormones (See under Hormones, Synthetic Substitutes and Antagonists)

- Radiopharmaceuticals, Diagnostic and Therapeutic; Antipolycythemics, Radioactive; Radiation Sensitizers and Protectants (See under Radiopharmaceuticals, Radiation Sensitizers and Protectives)

Autonomics

Stimulate or depress sympathetic or parasympathetic systems.

Includes

- Adrenergics (Sympathomimetics)
- Antiadrenergics (Sympatholytics)
- Anticholinergics (Parasympatholytics)
- Cholinergics (Parasympathomimetics)

Excludes

- Antihypertensives (See under Cardiovascular Drugs)
- Antiparkinsonian Drugs (See under Central and Peripheral Nervous System Drugs)
- Antispasmodics, Gastrointestinal (See under Gastrointestinal Drugs)
- Antispasmodics, Urinary System (See under Urinary System Drugs)
- Bronchodilators (See under Respiratory Drugs)
- Mydriatics and Miotics specifically formulated for topical application to the eye (See under Ophthalmics)
- Vasoconstrictors and Vasodilators (See under Cardiovascular Drugs)

Cardiovascular Drugs

Primarily affect the heart and blood vessels excluding blood and the urinary system.

Includes

- Antiarrhythmics
- Antihypertensives
- Capillary Fragility Agents
- Cardiotonics
- Sclerosing Solutions
- Vasoconstrictors
- Vasodilators
- Vasopressors (Antihypotensives)

Excludes

- Agents which alter serum and tissue cholesterol levels (See under Metabolics, Electrolytes, Calorics and Nutrients)
- Diuretics (See under Urinary System Drugs)

Central and Peripheral Nervous System Drugs

Primarily alter the function of the brain, spinal cord or peripheral nerves (Autonomic Nervous System excluded).

Includes

- Analeptics
- Analgesics and Antipyretics
- Anesthetics
  - General
  - Local
- Anticonvulsants
- Antiparkinsonian Drugs
- Sedatives and Hypnotics

Excludes

- Antiemetics; Emetics; and Antispasmodics, Gastrointestinal (See under Gastrointestinal Drugs)
- Antihistaminics (See under Antiallergics)
- Appetite Depressants (See under Gastrointestinal Drugs)
- Bronchodilators and Antitussives (See under Respiratory Drugs)
- Psychopharmacologic Drugs (See under Psychopharmacologics)
- Skeletal Muscle Relaxants and Stimulants (See under Musculoskeletal Drugs)

Dental and Oral Drugs

Primarily for the prevention or treatment of disease processes of dental structures (teeth, sockets and gingival tissues), and of the mouth.

Includes

- Anti-Infectives, Dental
- Cariostatics
- Dental Protectants
- Dentifrices
- Denture Adhesives
- Mouthwashes

Excludes

- Adjuvants used in dentistry, such as analgesics and sedatives (See under Central and Peripheral Nervous System)
- General Antibacterials (See under Anti-infectives)
- Hemostatics (See under Hematics)
- Prosthetic Devices (See under Devices, Prosthetics, and Other Medical Supplies)

Dermatologics

Prevent, modify or treat disease processes of the skin; or applied for protective, hygienic or cosmetic purposes.

Includes
- Abrasives
- Anti-infectives, Dermatologic
- Anti-inflammatories, Topical
- Antipruritics
- Antipsoriatics
- Antiseborrheics
- Astringents, Dermal
- Caustics
- Cleansing Agents
- Deodorants and Antiperspirants
- Depilatories
- Escharotics
- Hypoallergenic Cosmetics
- Keratolytics
- Keratoplastics
- Pigmentation Agents
- Protectives and Maskers
- Tissue Proliferants
- Vesicants

Excludes
- Anti-inflammatories, Systemic (See under Hormones, Synthetic Substitutes and Antagonists; Ophthalmics; and Ear, Nose and Throat Drugs)
- Antifungals (See under Anti-infectives)
- Counterirritants (See under Musculoskeletal Drugs)
- Radiation Sensitizers and Protectants (See under Radiopharmaceuticals, Radiation Sensitizers and Protectives)
- Sclerosing Solutions (See under Cardiovascular Drugs)
- Topical Antiseptics and Germicides other than Dermatologics (See under Anti-infectives)

Devices, Prosthetics and Other Medical Supplies

Adjuvants, as distinct from medicinal substances, used in the prevention, management or treatment of diseased states. Also includes contraceptive devices.

Includes
- Devices
- Medical Supplies
- Prosthetics

Diagnostics

Aid the analysis and evaluation of physiological states and bodily functions for diagnostic purposes, and the monitoring of the course of disease processes.

Includes
- Diagnostic Dyes
- Diagnostic Skin Testing Preparations
- Test Reagents (Papers, Tablets, etc.)
- Pregnancy Tests
- Radio-opaques
- Tissue/Organ Function Tests

Excludes
- Radiopharmaceuticals, Diagnostic (See under Radiopharmaceuticals, Radiation Sensitizers and Protectives)

Ear, Nose and Throat Drugs

To prevent or treat disease processes occurring within the ear, nose and throat by topical application.

Includes
- Analgesics, ENT
- Anti-infectives, ENT
- Anti-inflammatory Agents, ENT
- Astringents, ENT
- Ceruminolytics
- Decongestants, Nasal
- Lubricants, ENT

Excludes
- Antihistaminics (See under Antiallergics)
- Dental Drugs (See under Dental and Oral Drugs)

Enzymes and Coenzymes

Catalyze or inhibit biochemical reactions directly or indirectly.

Includes
- Coenzymes
- Enzymes
- Enzyme Activators
- Enzyme Precursors

Excludes
- Enzyme Inhibitors (See under Diuretics; Ophthalmics; and Psychopharmacologics)
- Pencillin Antidotes (See under Antidotes, Deterrents and Poison Control Agents)

Gastrointestinal Drugs

Affect the gastrointestinal system (including the tract), stimulate or depress appetite, prevent nausea and vomiting, or treat hemorrhoids.

Includes
- Acidifiers, Gastric
- Adsorbents
- Antacids, Gastric
- Antidiarrheals
- Antiemetics

- Antiflatulants
- Anti-infectives, Gastrointestinal
- Antispasmodics, Gastrointestinal (Anticholinergics)
- Appetite Depressants
- Appetite Stimulants
- Digestants
- Flora Modifiers and Replacements
- Hemorrhoidal Preparations
- Cathartics and Evacuants

Excludes

- Emetics (See under Antidotes, Deterrents and Poison Control Agents)
- Sclerosing Solutions (See under Cardiovascular Drugs)

Genital System Drugs

Prevent conception, modify ovulation and treat disease processes of the genital system (including the tract), or affect uterine function.

Includes

- Antifertility Drugs (Contraceptives)
- Anti-infectives, Urethral and Vaginal Topicals
- Fertility Drugs
- Lubricants
- Oxytocics
- Uterine Relaxants
- Vaginal Astringents and Cleansers

Excludes

- Devices (See under Devices, Prosthetics and Other Medical Supplies)

Hematics

Affect blood volume and cell production, hemoglobin content, and coagulation.

Includes

- Antianemics
- Anticoagulants
- Antipolycythemics, Non-Radioactive
- Blood Replenishers (Whole Blood, Blood Fractions)
- Blood Volume Expanders (Supporters)
- Hemostatics

Excludes

- Anticoagulant Antagonists (See under Antidotes, Deterrents and Poison Control Agents)
- Antipolycythemics, Radioactive (See under Radiopharmaceuticals, Radiation Sensitizers and Protectives)
- Enzymes (See under Enzymes and Coenzymes)

Hormones, Synthetic Substitutes and Antagonists

Modify, or replace the function of endocrine glands or the activity of their secreted hormones.

Includes

- Adrenal Cortex Hormones (Anti-inflammatory Steroids)
- Hormone Antagonists
- Oral Hypoglycemics
- Ovarian Hormones
- Pancreatic Hormones
- Parathyroid Hormones
- Placental Hormones
- Pituitary Hormones, Anterior
- Testicular Hormones
- Thyroid Hormones

Excludes

- Anabolic Drugs (See under Metabolics, Electrolytes, Calorics and Nutrients)
- Antidiuretic Hormones (See under Antidiuretics, Urinary System Drugs)
- Anti-inflammatoryHormones, Topical (See under Dermatologics; Ophthalmics; Ear, Nose and Throat Drugs)
- Fertility Drugs (See under Genital System Drugs)
- Hormones of the Adrenal Medulla, Adrenergics and Antiadrenergics (See under Autonomics)
- Oxytocics and Uterine Relaxants (See under Genital System Drugs)

Immunologicals

Confer active or passive immunity.

Includes

- Antitoxins
- Immune Serums
- Toxoids
- Vaccines

Excludes

- Allergenic Extracts, Desensitizing (See under Antiallergics)
- Antivenins (See under Antidotes, Deterrents and Poison Control Agents)
- Biological products used diagnostically (See under Diagnostics)

Metabolics, Electrolytes, Calorics and Nutrients

Supplement dietary requirements, modify caloric intake, correct electrolyte or fluid abnormalities, or modify serum and tissue levels of cholesterol, lipids, uric acid and other constituents.

- *Includes*
  - Anabolic Drugs
  - Antihyperlipemics
  - Dietary Supplements
    - Carbohydrates
    - Lipids (oils, fats, etc.)
    - Minerals
    - Proteins
    - Vitamins
  - Dietetic Preparations
    - Salt Substitutes
    - Sugar Substitutes
  - Electrolytes and Fluid Balance Drugs
    - Acidifiers, Systemic
    - Alkalizers, Systemic
    - Electrolyte Removers
    - Fluid and Electrolyte Replenishers
  - Hypouricemics
    - Uricosurics
  - Lipotropics
- *Excludes*
  - Blood Volume Expanders and Replenishers (See under Hematics)
  - Diuretics and Antidiuretic Hormones (See under Urinary System Drugs)
  - Iron Preparations (See under Hematics)
  - Vitamin K (See under Antidotes, Deterrents and Poison Control Agents)

Musculoskeletal Drugs

Treat disorders of musculoskeletal tissues and structures, or produce skeletal muscle relaxation for surgical procedures.

- *Includes*
  - Antirheumatics
  - Bone Preparations
  - Counterirritants
  - Skeletal Muscle Relaxants (Curare, etc.)
  - Skeletal Muscle Stimulants
- *Excludes*
  - Analgesics and Antipyretics (See under Central and Peripheral Nervous System Drugs)
  - Anti-inflammatory Steroids (See under Hormones, Synthetic Substitutes and Antagonists)
  - Antiparkinsonian Drugs (See under Central and Peripheral Nervous System Drugs)

Ophthalmics

Prevent, treat or modify disease processes of the eye and its adjacent tissues.

- *Includes*
  - Antiglaucoma Agents
  - Anti-infectives, Ophthalmic
  - Anti-inflammatory Agents, Ophthalmic
  - Astringents, Ophthalmic
  - Contact Lens Solutions
  - Eye Washes
  - Miotics
  - Mydriatics
- *Excludes*
  - Ophthalmic preparations used diagnostically (See under Diagnostics)

Pharmaceutic Aids

Improve the compounding, taste, appearance and stability of pharmaceutical preparations.

- *Includes*
  - Coloring Agents
  - Diluting Agents (Vehicles and Bases)
  - Emulsifying and Suspending Agents
  - Flavoring Agents
  - Perfuming Agents
  - Preserving Agents
  - Wetting Agents

Psychopharmacologics

Manage or treat psychiatric disorders.

- *Includes*
  - Antianxiety Agents
  - Antidepressants
  - Antipsychotics
  - Psychotomimetics
- *Excludes*
  - Analeptics (See under Central and Peripheral Nervous System Drugs)
  - Sedatives and Hypnotics (See under Central and Peripheral Nervous System Drugs)

Radiopharmaceuticals, Radiation Sensitizers and Protectives

Radioactive drugs used for diagnosis and therapy, and other agents employed to modify sensitivity to radiation.

- *Includes*
  - Antipolycythemics, Radioactive
  - Radiation Protectants
  - Radiation Sensitizers
  - Radiopharmaceuticals
    - Diagnostic
    - Therapeutic
- *Excludes*
  - Radio-Opaques (See under Diagnostics)

RESPIRATORY DRUGS

Manage or treat diseases of the respiratory tract.

Includes

- Antitussives
- Bronchodilators
- Expectorants
- Mucolytics
- Respiratory Gases

Excludes

- Analeptics (See under Central and Peripheral Nervous System Drugs)
- Antihistaminics (See under Antiallergics)
- Anti-infectives (See under Anti-infectives)
- Nasal Decongestants (See under Ear, Nose and Throat Drugs)

URINARY SYSTEM DRUGS

Alter the production or excretion of urine or otherwise affect the urinary system (including the tract).

Includes

- Analgesics, Urinary System
- Antidiuretics
- Anti-infectives, Urinary System
- Antispasmodics, Urinary System
- Diuretics

Excludes

- Hypouricemics (See under Metabolics, Electrolytes, Calorics and Nutrients)
- Systemic Acidifiers and Alkalizers (See under Metabolics, Electrolytes, Calorics and Nutrients)

CHAPTER 8

UTILIZATION REVIEW

Utilization review is a dynamic process that commences with a study of paid claims and ultimately results in a course of necessary remedial actions.

Under drug insurance, these efforts are intended primarily to improve the quality of health care received by patients and, at the same time, to minimize program expenditures. An integral part of the latter goal involves minimizing program abuse and fraud.[a]

Recognizing the importance of utilization review and its special role in improving the quality of health care in Title XIX programs, the Congress has required the provision of "such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy, and quality of care." [1]

The investment of drug insurance funds in such activities is obviously justified to the extent that the results would be worth the effort and the expense—that is, that a favorable benefit-to-cost ratio would be achieved. But, in measuring the value of utilization review, it must be recognized that a substantial dividend would be represented by the feedback of information to schools of medicine and pharmacy, and to industry. There is likely to be maximum effectiveness of these review activities when there is a continuous flow of significant findings to physicians and others concerned with the determination of benefits under a drug insurance program. By making the results of review studies available to educational institutions responsible for training professional health care workers, and facilitating an analysis of the characteristics of drug use, improvement in both theory and practice would become possible.

Essential to the success of a drug utilization review program is the establishment of the scientific basis—together with development of the necessary standards and guidelines—for relating drug therapy to the medical status of patients. Accordingly, the first step would be the preparation of specifications which delineate what has been termed *rational drug therapy*. This has been considered to mean prescribing the right drug for the right patient, at the right time, in the right amounts, and with due consideration of relative costs.[2]

It is evident, however, that the practice of medicine has aspects characteristic of both art and science. For this reason, at least during the early stages of drug utilization review, the greatest progress is likely to come not so much from enhancing rational drug prescribing, as from minimizing *irrational* prescribing. Here, then, the first step would be the definition of prescribing patterns which are readily recognizable and definable generally by the medical community as irrational. Succeeding steps would be directed toward the eventual attainment of rational prescribing as quickly as analysis of claims data and medical progress permit.

Problems and Practices

Problems of irrational drug therapy which now exist in medical practice—and which would be intensified in a drug insurance program—have already drawn the attention of clinicians.

One physician has reported:

> "... a group of general practitioners participated in an analysis of their own prescribing habits. They found that only about one-third of their prescriptions were for drugs which they believed had a known specific or probably beneficial effect on conditions for which they were being prescribed." [3]

Another doctor, implying that the statistical probability of a physician selecting the correct drug is not likely to be as high as it should, said this:

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[a] Certain screening functions aimed at cost control or fraud detection may be initiated before payment of the drug claim.

[1] Public Law 90-248, Section 237.

[2] Task Force on Prescription Drugs: "The Drug Prescribers," U.S. Government Printing Office, Washington, D.C., 1968, p. 3.

[3] White, Kerr L.: Statement in U.S. House of Representatives, Committee on Interstate and Foreign Commerce: "Partnership for Health Amendments of 1967," U.S. Government Printing Office, Washington, D.C., 1967, p. 277.

> "No physician can be expected to be familiar with the 15,000 or 16,000 different drug products and dosage forms listed in various reference directories, nor can he know very much about each of the 1,200 or so agents most commonly used."[4]

But irrational prescribing has not been discussed merely in general terms. Certain specific examples have been examined, and—at least in some cases—solutions have been proposed.

Product Deterioration. There are some drugs which are known to deteriorate when improperly stored. In many instances this problem can be controlled simply by having the pharmacist print on the label a notice that the medication should be discarded on or before a specified date. In other cases, a utilization review committee might wish to study drugs known to be particularly susceptible to deterioration and make appropriate recommendations on the maximum quantities to be dispensed.

Dosage Adjustment. With the use of a number of drugs—such as antihypertensive and diuretic agents—it is the general practice of physicians to gauge the patient's reaction to different dosage levels over a period of time so the intended therapeutic effect can best be achieved. It may also be necessary to establish patient tolerance to different combinations of drugs, and the like.[5] Under such conditions, an original prescription could be written for a starting amount of the drug, with subsequent orders adjusted in the light of the original response. Where no such titration is undertaken, the prescribing could possibly be construed as irrational.

An evaluation of this problem might start with an analysis of prescribing patterns for the initial supply of particular drugs, aimed at determining the extent to which some physicians seem to follow the titration principle while others more frequently order a standard supply over a prolonged period. Such a study might accumulate information such as that presented in Table 4, which illustrates the number of units ordered for three selected drugs—conjugated estrogens, hydrochlorothiazide, and sodium warfarin—as found in one recent study. Here, a review committee would observe that more than 85 percent of the prescription orders for each of these drugs called for more than 30 tablets; the committee could then specify any needed research to establish the rationality or irrationality of these patterns in view of clinical effects, adverse reactions, general safety, and overall patient expenses.

Table 4

Number of Prescription Orders Filled for Three Selected Drug Products, by Quantity Dispensed Through One Retail Outlet, February 1968[a]

Quantity of Drug Supplied (Number of Units)	Number of Prescription Orders		
	Conjugated Estrogens	Hydrochlorothiazide	Sodium Warfarin
20	37	9	11
30	76	98	31
40	22	15	6
50	122	197	95
60	66	95	33
80	4	4	0
90	4	4	0
100	470	615	437
120	5	8	1
130	1	0	0
150	6	4	1
200	16	78	37
300	2	4	2

[a] Source: Browning, James L. (Drug Service, National Retired Teachers Association and American Association of Retired Persons): Personal Communication, 1968.

In this connection, it is important to note that data obtained in the early stages of utilization review are seldom conclusive; more often, they merely highlight those areas in which more intensive study seems justified.

Patient adjustment to drug dosage has still another dimension. Sudden withdrawal of a drug may also be hazardous, as in the case of certain corticosteroids. Thus, it has been reported: "Patients receiving long term therapy should be informed that these drugs must never be terminated suddenly . . . Such action almost always causes a severe exacerbation of symptoms and may precipitate overt adrenocortical failure."[6]

Combination Drugs. A number of experts have called attention to the serious limitations associated with the prescribing of combination products.[7-9] In the case of antimicrobial drug combinations, the problem is especially important since their use in some circumstances may lead to a false sense of security and discourage efforts to establish a specific etiologic diagnosis.[10]

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[4] Cluff, Leighton E.: "The Prescribing Habits of Physicians," Hospital Practice 2:101 (September 1967).

[5] Russell, R. Patterson: "Hypertension," in Harvey, A. McGehee, *et al.*: "The Principles and Practice of Medicine," Appleton-Century-Crofts, New York, 17th ed., 1968. p. 301.

[6] Holley, Howard L., and Hogan, Robert S.: "Present-Day Management of Rheumatoid Arthritis," GP 30:115–125 (July 1964).

An additional hazard has been described as follows:

> "Another risk associated with the use of combination products is derived from the fact that many brand names give no indication of the active ingredients. Many of these items combine a variety of drugs and the physician can often lose sight of the various components. For example, meprobamate can be prescribed by at least 33 different names, *some* of which combine the basic product with a variety of other drugs. Thus a physician could prescribe one of these auxiliary ingredients *again* in a separate preparation." [11]

Multiple Prescribing. Prescribing more than one drug to be taken at the same time raises at least two questions which may be properly concerned in utilization review—

- Will the two drugs together promote a more certain and more rapid recovery than either one used alone?
- Will the simultaneous use of the drugs introduce an additional risk not justified by the seriousness of the illness?

The potential hazards have been a matter of concern to physicians. While each drug may be safe in its own right, it has been stated, the mixture of drugs may prove unsafe.[12]

It has also been said:

> "For example, a heart patient who develops arthritis may find himself taking an antiarthritic drug on top of his anticoagulant. The one drug may potentiate, or increase the effect of, the other, so that an ordinary safe therapeutic dose can become a dangerous overdose." [13]

The relation between the number of drugs used and the probability of adverse reactions has been demonstrated in a Johns Hopkins study. Of those hospitalized patients receiving less than 11 drugs per confinement, it was reported, nearly 6 percent experienced adverse reactions. For those receiving 16 or more medications, however, the risk of an adverse reaction was *seven times greater*.[14] The problem of adverse drug reactions, the study showed, was particularly serious for elderly patients on multiple prescriptions.[15]

Another potential hazard is this:

> "The use of several drugs at once may imply uncertainty and an absence of adequate diagnosis. It may be less than rational in that no drug is given a chance to work effectively, and in the worst case the drugs may cancel each other. Numbers alone are a screening device to identify cases for further [utilization review] study."[16]

There are likewise grounds for believing that multiple prescribing may impede rather than facilitate recovery. For example, one writer reported, "A patient with mental confusion was receiving nine different drugs. When all drugs were canceled except digitalis, the confusion cleared." [17]

Multiple prescribing would obviously raise the possibility or probability of unnecessary drug costs. In the case of elderly patients, it would also raise the possibility of patient confusion and resultant patient errors in the correct use of the drugs.[a]

The extent of multiple prescribing has not been adequately studied, but an indication of its frequency is available in the results of a recent survey of prescribing habits in Pennsylvania. Among patients aged 65 and over, it was found, 81 percent were taking prescription drugs during the survey period, and 65 percent of these individuals were using more than one drug at the same time. Among this latter group, the number of concurrent pre-

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[7] The British Ministry of Health has compiled a list of 102 drugs involving primarily combination products which should not be prescribed. See The Economist 223: 487–488 (April 29, 1967).

[8] Kunin, Calvin M.: Statement in U.S. Senate, Subcommittee on Monopoly, Select Committee on Small Business: "Competitive Problems in the Drug Industry," U.S. Government Printing Office, Washington, D.C., 1967, Part 2, pp. 731–732.

[9] Drug Trade News (November 6, 1967).

[10] *Ibid.*

[11] Azarnoff, Daniel L.; Hunninglake, Donald B.; and Wortman, Jack: "Prescription Writing by Generic Name and Drug Cost," Journal of Chronic Diseases 19:1256 (November–December 1966).

[12] U.S. Senate, Subcommittee on Reorganization and International Organizations, Committee on Government Operations: "Interagency Drug Coordination," U.S. Government Printing Office, Washington, D.C., 1966, p. 183.

[13] Drug News Weekly (November 20, 1967).

[14] Cluff, Leighton E.: "The Prescribing Habits of Physicians," *op. cit.*, p. 101.

[15] *Ibid.*, p. 102.

[16] Muller, Charlotte F.: "The Study of Prescribing as a Technic of Examining a Medical Care System," American Journal of Public Health 57:2121 (December 1967).

[17] DeGroot, Leslie J. (ed.): "Medical Care," C. C. Thomas, Springfield, Illinois, 1967, p. 207.

[a] Many dimensions of this problem are outlined in Medical Tribune 4:11 (February 1, 1963).

scriptions ranged from two to eight.[18] Other sources have reported instances in which a patient was taking as many as 60 drugs simultaneously.[19]

Appropriate Dosage Strength. Another area calling for utilization review is that of prescribed dosage strength. For example, a prescription could call for two 0.25 mg tablets to be taken after each meal, or for one 0.50 mg tablet. Under an insurance program, if the same number of tablets were supplied under either case, the program would have to pay double dispensing charges for the same total amount of the drug if the 0.25 mg size were prescribed. If co-payment were required, out-of-pocket expenses of the beneficiary would similarly be double.

Appropriate Drug Selection. A major function of utilization review would be an assessment of the appropriateness of the prescribed drug for its intended therapeutic effect. A well-designed review program, for example, should provide the means of comparing the actual clinical uses of a drug with the indications specified in its approved label. One such comparison showed that from 17 to 27 percent of the use of three tranquilizers was for daytime sedation, although this was an application neither advertised nor recommended by the manufacturers of the products.[20]

A more well-known illustration of such a discrepancy involves the antibiotic, chloramphenicol. On the basis of statistics indicating toxic side-effects associated with this agent, it has been recommended that chloramphenicol should never be used except for the treatment of typhoid fever and a few relatively rare infections, yet it has been widely applied in the treatment of many diseases. In commenting on such use, a report in the *Journal of the American Medical Association* stated:

> "By some means, whether by regulation or self-discipline, promiscuous use of the drug should be avoided and its use restricted to impelling circumstances, i.e., for conditions in which no other antibiotic is currently effective." [21]

Obviously, utilization review—and much additional scientific study—would be required to clarify such situations.

Categorical Prescribing Patterns. The administrator of a drug program can be expected to develop prescribing profiles so that reviews may be undertaken in terms of physician specialty, geographic area, etc. Comparison of such profiles is likely to be especially important in considering such matters as the prescribing habits of dispensing physicians as compared to those of nondispensing physicians.

Telephone Prescribing. Over one-third of all prescriptions are ordered by telephone. In some urban areas, the figure may be closer to 50 percent. A number of questions have been raised about the relation of such orders to rational—or irrational—prescribing. One of the major areas for study under utilization review might therefore be found in the characteristics associated with telephone prescriptions in comparison with those initiated in writing.

Some of the problems that may warrant review are these:

- Was the patient personally examined by the physician before the telephone order was placed? In light of the drug prescribed, was it essential that a visit take place?
- How do prescriptions generated by an office visit compare with those initiated without one?
- What procedures were followed to ensure that the patient was given the proper medication? Are dispensing errors likely to be more or less frequent with telephone prescriptions than with written orders?
- What characteristics are associated with physicians, patients and pharmacists who are frequently involved in telephone prescribing?
- Are certain illnesses and certain drugs typically associated with telephone prescribing?
- Are refills rather than original orders more frequently involved with telephone prescribing?

Rational Use of Psychotropic Drugs. Particular attention has been directed toward the appropriate use of the psychopharmacological or psychotropic drugs—the antianxiety drugs, the antidepressants, and the antipsychotic agents.[22] As noted elsewhere, these substances represent a substantial portion of the drugs most frequently used by the elderly, and thus account for a large amount of their drug expenses.[23] In addition, their use would appear to be associated in at least some instances with notably irrational prescribing—the wrong drug for the wrong patient, in the wrong amounts, for the wrong period of time, and with little or no consideration of relative costs.

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[18] McEvilla, Joseph D. (University of Pittsburgh): Personal Communication, 1968.

[19] Cluff, Leighton E.: "Problems with Drugs," in "Proceedings: Conference on Continuing Education for Physicians in the Use of Drugs," a meeting sponsored jointly by the Drug Research Board, National Academy of Sciences-National Research Council; U.S. Food & Drug Administration; and Regional Medical Programs, U.S. Health Services and Mental Health Administration, Washington, D.C. (February 5, 1969).

[20] Done, Arthur A.: "Differences Between Advertised and Medical Uses of Drugs," Journal of Advertising Research 1:18 (September 1960).

[21] Dameshek, William: "Chloramphenicol—A New Warning," Journal of the American Medical Association 174:1853–1854 (December 3, 1960).

[22] For a comprehensive evaluation of psychotropic drugs, see Veterans Administration, Department of Medicine and Surgery: "Medical Bulletin MB–11," Washington, D.C., September 15, 1966.

In any utilization review program, attention might properly be focused on such points as these:[24]

- The prescribing of drugs that are contraindicated in the condition as diagnosed, or that have been found to be ineffective.
- The use of psychotropic drugs—especially for prolonged periods—in patients deemed to be particularly dependency-prone.
- The use of such drugs, often at high prices, when low-cost generics or even placebos may be as useful or even clinically preferable.
- Selection of the appropriate dosage levels, with suitable modifications from time to time, as indicated for the different psychotropic agents.
- Restriction of the use of alcohol by patients taking antianxiety drugs.
- Restriction of the use of antidepressant drugs in combination with monoamine oxidase inhibitors.

In these and similar situations, much additional research would be required before meaningful guidelines can be established for either short-term or long-term therapy.

Patient Drug Use Records. Essential for effective utilization review—and for rational prescribing in general—are readily accessible records on the use of drugs by patients, and any adverse reactions, sensitivities, or other effects which may have been observed.

Some have recommended that community pharmacists should maintain a "family drug consumption and sensitivity record" on a continuing basis.[25] Before filling a prescription, a pharmacist using such an approach would refer to the record in order to guard against furnishing a product likely to result in undesirable reactions with other drugs being taken by the patient,[26] a product to which the patient is known or suspected to be sensitive, or representing an unintentional overdose, and calling such a situation to the attention of the prescriber wherever indicated.

The achievement of such goals in this manner would raise a number of practical problems. Since many patients do not always patronize the same pharmacy, it would be difficult to depend on the "family record" as a certain or even effective means of controlling these types of irrational therapy. Even if an insurance program designated particular pharmacies in each area that beneficiaries were required to use in order to obtain covered drug services, there is still a question whether the necessary recordkeeping could not be handled more efficiently in other ways.

One possibility is the development of a patient drug history data-bank as a byproduct of the claims processing system. Such a data-bank could be established by using a terminal central computer network connecting pharmacy, physician and hospital locations. All drug records could be entered into the system and retrieved as necessary.

In the case of patients with scheduled appointments, for example, the physician could query the data-bank the night before the appointment and have available a print-out of all prescriptions filled for that patient, together with any adverse reactions reported by himself or other physicians. For the vast majority of physicians, it is estimated that 95 percent of their office consultations are scheduled in advance, thus providing sufficient lead time for the data-bank system queries to be handled during periods of low demand on computer time. In special circumstances, the needed information could be processed on peak computer time, although at somewhat higher cost.

The concept of a data-bank for social science information has been examined intensively by a committee of the National Research Council. The Council's report noted that ". . . there can be no doubt that somehow the horse-and-buggy methods of social researches will have to give way to new methods made possible by modern communications technology." [27] Access to drug histories by the application of such modern technology would be of significant help to physicians and pharmacists, serve as a valuable step in achieving rational drug therapy, and contribute to effective drug utilization review.[a]

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[23] Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, pp. 35, 38 *et seq.*

[24] Veterans Administration, Department of Medicine and Surgery: "Medical Bulletin MB–11," *op. cit.*

[25] Rosner, Martin M.: "Attitudes Toward Maintaining Family Records on Drug Sensitivities," Journal of the American Pharmaceutical Association (NS) 4: 169–172, 175 (April 1964).

[26] For a detailed discussion, see Ellenhorn, Matthew J., and Sternad, Frank A.: "Problems of Drug Interaction," Journal of the American Pharmaceutical Association (NS) 6: 62 (February 1966).

[27] National Academy of Sciences: "Communication Systems and Resources in the Behavorial Sciences," Washington, D.C., 1967, p. ii.

Alternative Approaches

The examples noted in the preceding section are merely illustrative of the many types of irrational prescribing that have caused serious concern among physicians; that have possibly resulted in injury, delayed recovery from illness, or even death; and that have needlessly inflated drug expenditures.

Some versions of irrational prescribing may reflect inadequate education,[28] inadequate sources of information,[29] or inadequate time for prescribers to keep up-to-date on both old and new drug products.[30] Some may reflect errors of omission or commission on the part of patients—the failure to follow directions, the incorrect use of correctly prescribed drugs, or the pressure exerted by patients on physicians to prescribe a drug where no drug is needed or to prescribe according to some current fad. Others may be associated with the unjustifiably optimistic or enthusiastic advertising or other promotional claims made by some drug manufacturers or their representatives.[31-32]

At least four different approaches for dealing with these problems may be considered: (a) maintain the present system, and impose no constraints; (b) improve the quality and quantity of training, especially in pharmacology, in medical and pharmacy schools; (c) restrict prescribing through the use of a formulary; and (d) implement effective programs of utilization review.

No Prescribing Restraints. From the point of view of a drug insurance program, there would undoubtedly be certain advantages in maintaining the traditional and simplified approach of perpetuating current prescribing patterns. Administrative costs of the program would be kept at a minimum, fewer obligations would be placed on the professional personnel in the program, and fewer charges would be brought on the basis of interference with medical practice. The problems associated with irrational prescribing, however, suggest that such inaction may be inconsistent with the promotion of better health care and the reduction of costs.

Although the use of formularies or utilization review may be construed in some quarters as interference with medical practice, such steps would be neither unprecedented nor necessarily disadvantageous. As will be noted below, formularies have been widely and effectively used in many hospitals and in nongovernmental and governmental drug programs, both to improve care and reduce costs. Precedents for utilization review may be found in many hospitals in this country and abroad, in the efforts of numerous hospital pharmacy and therapeutics committees, in the reviews of medical services initiated by some local medical societies, and in the drug review procedures used in Great Britain and other countries. The fact that these and similar efforts have been undertaken may suggest that some physicians already recognize an unrestricted approach to prescribing does not necessarily result in attaining the highest levels of health care.

Improved Education and Information. Improving the undergraduate and postgraduate training of physicians and pharmacists, providing them with a greater fund of drug knowledge, instilling in them the appropriate attitudes towards drugs and especially towards drug promotional claims, and making readily available complete, objective, up-to-date information on drugs and drug prices are all fundamental in achieving the goal of rational prescribing.[33]

It seems evident, however, that such techniques—as valuable as they will be for the long run—may have limited impact in raising the standards of drug therapy during the next decade or so.

Use of Formularies. As noted elsewhere,[34] drug formularies—even when they are not restrictive—are thought by their proponents to have a useful role in the promotion of rational prescribing.

> "The formulary system is a method used by the medical staff of a hospital, working through a Pharmacy and Therapeutics Committee, to evaluate and to select, from among the numerous medicinal agents available, those that are considered most useful therapeutically and to

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[a] See pp. 70 *et seq.*

[28] "The Drug Prescribers," *op. cit.*, pp. 6–8.

[29] *Ibid.*, pp. 9–16.

[30] *Ibid.*, p. 9.

[31] *Ibid.*, pp. 13–15.

[32] Task Force on Prescription Drugs: "The Drug Makers and the Drug Distributors," U.S. Government Printing Office, Washington, D.C., 1968, pp. 28–29.

[33] "The Drug Prescribers," *op. cit.*, pp. 6–8.

[34] *Ibid.*, pp. 12, 43 *et seq.*

list dosage forms in which they may be administered most effectively."[35]

Widely used in major American hospitals, formularies also play a role in various drug insurance programs, both in this country and abroad.[36] Whether or not they could be similarly utilized in general nonhospital-based practice is now under consideration, with particular interest expressed in the development of formularies through joint pharmacist-physician cooperation at the county or State level.[37]

Whether a formulary in itself—without utilization review and peer judgments—will promote rational prescribing appears doubtful. It remains to be determined whether or not an effective utilization review program can be instituted without use of a formulary.

Use of Utilization Review. In the preceding sections, attention has been devoted to the general purposes of drug utilization review, and to some of the problems that might be studied under such a program. The implementation of utilization review itself may now be examined in some detail.[a]

The approach to utilization review [38–42] is quite different from that involving a study of utilization in itself. A program covering the latter implies the examination of health care claims as related to various socio-economic characteristics which govern program experience—for example, the extent to which age and sex may influence insurance expenditures. In contrast, utilization review focuses primarily on those problems which, if brought under control, hold promise for improving patient health.

Utilization review is concerned secondarily with those measures which will conserve insurance funds as long as the basic goal of improved patient health is supported. It implies further that attention will be given to a third aspect which may not necessarily be covered under the two functions defined above—namely, the detection and resolution of problems concerning program abuse and fraud. To the extent that this latter function is well developed and publicized, it may be assumed that the inclination to defraud the insurance program would be at a minimum.

Prudent utilization review implies that rules, regulations and educational guidelines would be established only when there is an objective basis for them. Consequently, it should be expected that only the most obvious problems would be handled during the early stages of review, while those requiring additional data or scientific support would be pursued after such information became available. Utilization review, therefore, is an evolving process for decision-making rather than a full set of procedures which can be dropped onto an insurance program during the first months of operation.

Utilization review is essentially a qualitative interpretation of quantitative data. It is likely to be most effective when adequate staff support and computer time is made available to carry out the planning and data preparation stages. During this period, health care analysts, statisticians and programmers would be expected to assume major responsibilities. Under drug insurance, they would be assisted through the use of consultative services provided by physicians, pharmacists and pharmacologists. Once the data preparation phase has progressed to an appropriate level—through the development of data profiles, establishment of statistical cutoff criteria to indicate significance of the quantitative base, etc.—the roles would be reversed. Then physicians and pharmacists would begin an evaluation of the data to determine how the practice of medicine in general and drug use in particular could be improved. Analysts and statisticians would be enlisted to explain levels of statistical significance, the need for any additional data to contribute to improved reliability, etc. Obvious problems would be singled out quickly for remedial action, while others would be studied for a longer period until decisions could be supported by a scientific basis.

In utilization review, it is assumed that professional judgments on claim information would be made at the local level. Certainly, it seems unlikely that many cases would require review beyond the State level. Because of the need for impersonal handling of problem cases, however, it also seems unlikely that decision-making can be expected to function well at a level lower than that of the State. The preparation of general guidelines for case investigation and interpretation at the national level should be useful, though, in aiding the review process.

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[35] American Society of Hospital Pharmacists: "American Hospital Formulary Service," American Society of Hospital Pharmacists, Washington, D.C., 1967. p. vii.

[36] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968.

[37] "The Drug Prescribers," *op. cit.*, p.13.

[a] In addition to the references specifically cited in this section, a number of additional references in this field are given at the end of the chapter.

[38] Donabedian, Avedis: "Evaluating the Quality of Medical Care," Milbank Memorial Fund Quarterly 44: Part 2, pp. 166–206 (July 1966).

[39] Wallace, J. Douglas: "Developing an Effective Utilization Review Program," Hospitals 41: 70–73 (November 16, 1967).

[40] American Medical Association: "Utilization Review," American Medical Association, Chicago, Ill., 1965, p. 116.

[41] "Utilization Review in Psychiatric Hospitals," Report of a conference, November 1967, sponsored jointly by the National Institute of Mental Health, the Division of Medical Care Administration, Public Health Service, and the American Psychiatric Association, Summer 1968.

[42] Francke, Don E.: "What are the Goals of the Pharmacy and Therapeutics Committee?" Hospitals 41: 99–101 (October 16, 1967).

An objective, scientific basis should support all actions. Care must be taken so that the limitations of therapy are not overemphasized, with the resultant creation of a climate militating against the most efficient use of drugs.[43] At the same time, the administrator of an insurance program would need to ensure that the professional review function does not drift into a position in which important problems remain unsolved through professional inaction. State medical and pharmaceutical boards and societies have not often been in the vanguard in the matter of member discipline or the implementation of educational programs based on findings of utilization review studies. Methods for reaching the professions and interpreting program findings must be improved.

It should be recognized that utilization review is never intended to be a substitute for poorly conceived programs or improper administration. It cannot be expected to counteract problems arising from such errors as improper payment because of beneficiary ineligibility, exclusion of the drug from coverage, vendor overpayment, etc. Moreover, a "reasonable charges" reimbursement system that accepts virtually all claims at par cannot then lean upon utilization review to control cost problems which may become apparent.

Utilization review methods, especially when data indicating medical condition of the patient are available, can be expected to make a major contribution toward improving patient care. Nevertheless, it should be recognized that maximum effectiveness requires an even broader data base than can be generated from drug insurance records. This point has been stressed by one authority:

> ". . . for fullest value, the use of drugs should be appraised in the context of the type and sequence of diagnostic tests performed and of nondrug therapies (such as surgery, physical medicine, electroshock, and psychotherapy) applied. Thus we are back to elements of the complete medical audit." [44]

Under a drug program for the elderly, utilization review is likely to be more complicated than if the program covered the entire population.

> "In general, the elderly are more sensitive to drugs than are younger adults and therefore lower dosages are recommended. Because the aged are more susceptible to the toxic properties of various compounds, drugs should be administered cautiously and the dosages adjusted to meet individual requirements. . . . The problem is most critical with respect to drugs that act on the central nervous system." [45]

Under drug insurance, the major focus of review is the attainment of more rational drug therapy both at the overt level of prescribing, dispensing, and consuming, and at the more basic level that involves the education of current and potential program participants. The educational aspect has many dimensions. One, for instance, is highlighted by the finding that 37 percent of a group of patients disregarded their doctor's advice.[46] Overlooking the medical implications of this result, it is evident that even if half of this proportion of elderly patients obtained prescriptions under a comprehensive insurance program and did not use them properly, nearly $200 million per year would be partially or totally wasted. It might seem that figures of this size would demand that utilization review be studied and implemented in its broadest sense.

Another feature of utilization review concerns its effect on the discretion of physicians in prescribing for their patients. Undoubtedly this discretion could be limited from time to time as members of a review committee endeavor to control irrational drug therapy by their colleagues. In such cases, though, physicians whose prescribing practices were subject to frequent and serious question would usually have an opportunity to justify such practices. If a restricted formulary were relied upon exclusively, however, a physician could be precluded from using his judgment for all those drugs *not* included in the formulary. Thus utilization review could be a technique to broaden the discretion of a physician in applying drug therapy, while a formulary could limit his discretion. In any case, it appears that use of a formulary under drug insurance would not obviate the need for utilization review, since many issues cannot be resolved simply by means of a formulary.[a]

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[43] Weston, Jean K.: "The Present Status of Adverse Drug Reaction Reporting," Journal of the American Medical Association 203: 91 (January 1, 1968).

[44] Muller, Charlotte F.: "The Study of Prescribing as a Technic of Examining a Medical Care System," *op. cit.*, p. 2121.

[45] Bender, A. Douglas: "Pharmacologic Aspects of Aging," Journal of the American Geriatrics Society 12: 128 (February 1964).

[46] Davis, Milton S.: "Variations in Patients' Compliance with Doctors' Advice: An Empirical Analysis of Patterns of Communication," American Journal of Public Health 58: 274–288 (February 1968).

Another characteristic of utilization review methodology involves the nature of program records. Obviously, the data must be accurately recorded and should be available for study soon after the pharmaceutical service has been rendered. Similarly, the data should be comprehensive enough to permit judgments on the degree to which rational drug therapy has been attained.

In the proposed data requirements listed for a drug insurance program, the only major item not required to complete the reimbursement and program audit responsibilities is "patient diagnosis." Such information would be needed, however, to transform utilization review from a useful function to a highly valuable function. With diagnostic information—or its equivalent—included as a part of the drug claim record, professional reviewers would have a more sound foundation for judging the appropriateness of the indicated therapy.

It has already been noted that a therapeutic classification designation might be used as a replacement for diagnostic findings or as an additional indicator.[b] The relative reliability and utility of such alternative approaches call for systematic research. There are many reasons why the diagnosis *per se* or the therapeutic classification of the drug should not appear on the prescription form. Under either method, an appropriate code number would suffice.

Although prescription screening is recognized as a valuable tool for health insurance programs,[47] it is limited in the fact that a drug program in itself will yield information that describes only the prescribing function. The reliability of reviewing drug data profiles would be improved if the base were as broad as possible—that is, if information on all patients, pharmacies and physicians participating in the drug program could be assembled and analyzed as necessary for review purposes. The reliability and validity of the drug utilization review function would be improved even further if complete medical records—hospital, physician office, nursing home, etc.—were available for peer review in difficult or questionable cases.

The former problem suggests that centralized administration of all government drug insurance coverage should be studied from the point of view of obtaining maximum benefits from utilization review. The latter problem, relating drug records to total health care records, suggests the need for a health care history data-bank which can be queried for information when detailed information is required. It is recognized, of course, that the use of data-banks for storing detailed health records and similar social science information may be a matter of some controversy. One of the most important issues involves the possible conflict between individual privacy and centralized data collection, especially by a governmental agency. It appears unlikely that such data-banks would be used in government programs until agreement has been reached on their appropriate role, and on the safeguards necessary to prevent abuse of these information sources.

In the same way, it is recognized that—at least in the United States—utilization review has thus far been found most effective and most acceptable in a hospital environment. In such a setting, reviews are conducted and judgments rendered by peer groups—by other internists, other surgeons, pathologists, pharmacologists, hospital pharmacists, and the like. When remedial efforts are taken, when guidelines are established, or when disciplinary steps are invoked, these, too, represent peer actions.

There are no reasons to assume *a priori* that such actions cannot be taken successfully in a nonhospital setting, perhaps on a community-wide basis, under the existing system of medical care in this country. Some local groups, such as certain county medical societies, have demonstrated their ability to deal effectively with unprofessional conduct or inferior medical practice, even without the close-knit organization of a hospital or group-practice staff.

For a successful drug utilization review program, it appears essential that appropriate professional personnel—competent and respected physicians, pharmacists and other professionals—be closely associated with all review and educational activities. Representatives of practicing physicians, pharmacy, medical and pharmacy school faculties, and suitable professional organizations would be expected to fill important roles in such efforts.

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[a] For example, a formulary that permitted drug X to be prescribed would not necessarily be able to control the quantity dispensed or assess its use in treating particular conditions. Nor could a formulary necessarily restrict the consumption of drugs Y and Z in conjunction with drug X.

[b] See p. 44.

[47] Muller, Charlotte F.: "Medical Review of Prescribing," *op. cit.*, p. 695.

In England, the philosophy of persuasion rather than coercion and the reliance on professional judgment rather than established rules has been a major characteristic of drug utilization review.[48] This is illustrated by the following summary of one stage in the English review procedure:

> "Periodically, doctors' frequency and cost of prescribing, related to the size of practice population, are compared with the averages for the area in which they practice. Those who exceed the area average by more than an agreed ratio (usually twenty-five percent) may be visited by a Ministry official to discuss the matter. If the deviation from the area average persists, individual practitioners may ultimately have to appear before their colleagues on the Local Medical Committee, and in grosser cases the Minister may be recommended to impose a fine. In many respects obviously the system is very fair in that the deviation from the local average has to be persistent over a period, and the initial visit by the Ministry's officer is very much concerned with the sympathetic discussion of problems rather than the allocation of blame. Moreover, at the crucial stage, formal hearings by the Local Medical Committee, the Ministry has to prove its case to the practitioners' local peers."[49]

As an example of one aspect of utilization review, the General Medical Service of Scotland has selected a number of techniques to help practitioners become aware of rational drug usage and the comparative advantages of different medications. It circulates pamphlets on drugs and trends in prescribing, classifies new proprietary preparations according to their therapeutic value, publishes information on comparative drug costs, and even provides refresher courses for general practitioners that are organized by the medical schools.[50]

Finally, it seems necessary that the utilization review responsibility be placed within the administrative agency, with the executive in charge of reviews reporting directly to the chief administrative official of the insurance program. Because of the importance which utilization review findings could have in determining policy, the function should be so placed within the organizational structure to ensure maximum effectiveness.

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[48] "Current American and Foreign Programs," *op. cit.*, p. 178.

[49] Clapp, Raymond F.: "Study of Drug Purchase Problems and Policies," U.S. Department of Health, Education, and Welfare, Welfare Administration, Washington, D.C., March 1966, p. 32.

[50] Clapp, Raymond F.: *Ibid.*, pp. 29–30.

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CHAPTER 9

PROGRAM COST ESTIMATES

The cost of an out-of-hospital prescription drug program under Medicare would depend mainly on two sets of factors—those that can be determined in large part by legislation and program regulations, and those that would reflect the needs and demands of patients, vendors and physicians, and that cannot be effectively influenced or controlled by rules and regulations.

In this chapter, attention is directed especially toward a number of important variables that could modify trends in drug utilization and prescription prices. These factors would be among the prime determinants of program expenses.

The analysis here assumes that a program would have these characteristics:

- It would reimburse vendors on a formula basis resulting in rather limited controls of actual market prices.
- It would feature a modest program of utilization review at the outset, certainly during the first year of operations.
- It would include a form of patient cost-sharing that would somewhat restrict utilization.
- It would cover all persons eligible for hospital insurance—that is, it would involve coverage under Part A of Medicare.
- It would accept participation of all qualified drug vendors.
- It would begin in January 1971.

Two forms of programs are considered. One would involve comprehensive coverage of most but not necessarily all prescribed drug products. The major exclusions would be such products as anti-obesity drugs, multiple vitamins, and similar noncritical or low priority drugs. The other would limit covered products to important maintenance drugs that would be needed primarily for the treatment of chronic illness, and that probably would be listed in an official formulary of eligible drugs. Any deviations from these or other assumptions noted below would naturally increase or decrease program expenditures accordingly.

In any such program, the estimated costs indicated below could be substantially reduced by a number of approaches. From a survey of available evidence from current governmental and private drug insurance programs [1-2] and hospital operations [3-10], it appears that use of a scientifically designed formulary to exclude certain combination products, duplicative drugs and noncritical products from Federal reimbursement would not only contribute significantly to rational prescribing but could yield overall savings of at least 10 percent.

In the same way, establishing product cost ranges reflecting the cost of drugs generally available by their generic names would save approximately 5 percent at the retail level.[11]

Savings also could be achieved by such approaches as government purchase, effective utilization review, and the cost determination of actual vendor dispensing expenses. In each such instance, the amount of savings would depend on the extent to which each approach might be utilized.

The Level of Drug Prices

It is presumed that the average insurance benefit would be strongly influenced by average prescription prices, which in turn would be influenced

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[1] Task Force on Prescription Drugs: "Current American and Foreign Programs," U.S. Government Printing Office, Washington, D.C., 1968, pp. 48–50, 58, 65, 78–80, 87–88, 128–130, 132, 139, 171, 182, 185, 188, 190.

[2] Task Force on Prescription Drugs: "The Drug Prescribers," U.S. Government Printing Office, Washington, D.C., 1968, pp. 46–49.

[3] U.S. Senate, Subcommittee on Monopoly, Select Committee on Small Business: "Competitive Problems in the Drug Industry," U.S. Government Printing Office, Washington, D.C., 1967 *et seq.*

[4] Cherkasky, Martin: Statement in U.S. Senate (3), pp. 672–674, 693.

[5] Francke, Don E.; Latiolais, Clifton, J.; Francke, Gloria N.; and Ho, Norman F. H.: "Mirror to Hospital Pharmacy," American Society of Hospital Pharmacists, Washington, D.C., 1964, pp. 139–155.

[6] Kunin, Calvin M.: Statement in U.S. Senate (3), Part 2, p. 731.

[7] McCarron, Margaret: Statement in U.S. Senate (3), Part 2, pp. 581–589.

[8] Modell, Walter: Statement in U.S. Senate (3), Part 1, pp. 294–295.

[9] Williams, Harry L.: Statement in U.S. Senate (3), Part 2, p. 467.

[10] "The Drug Prescribers," *op. cit.*, pp. 12–13, 43–44.

[11] Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, pp. 36–37.

by a number of factors. Important among them are the following:

- Overall scope of drug product coverage, including the extent to which prescribed over-the-counter products are covered.
- The extent of physician-dispensing, and any controls applied to it.
- The possible growth of mail-order and chain-store dispensing.
- Any cost regulations regarding product acquisition.
- Reimbursement based upon a flat dispensing fee rather than a percentage markup.
- The extent to which delivery services are reflected in the reimbursement formula.
- Any changes in quantities of medication prescribed per prescription.
- The quantity of medication allowed per prescription.
- Any change in price competition within the drug industry resulting from tariff and import regulations, patent expirations, etc.
- Effectiveness of pharmacist-patient relations.
- The discovery of new drugs and a shift to these items in place of older products.

The average prescription price of drugs purchased by the elderly is currently about 10 percent higher than that paid by individuals of all ages.[12] The latter figure, according to three different sources, was about $3.60 in 1967.[a] Consequently, it appears that the average price paid by the elderly for prescribed drugs in 1967 was about $4.00. Table 5 summarizes the estimates of average costs per prescription in 1971.

In attempting to weigh the effect of the factors noted above, it may be assumed that, in the absence of a Medicare drug program, a slight increase in average price (estimated to be about 2 percent per year) will occur. Such a change would indicate an increase in the average price for the elderly to approximately $4.30 per prescription. An unrestrained program might inflate prices by another 8 percent, raising the market price as high as $4.65 by 1971. On the assumption that an insurance program would have some restraining influence on average prescription prices paid by the beneficiaries, however, it seems appropriate for planning purposes to reduce the estimate and use a figure of $4.00 for a comprehensive program. For a program limited to coverage of important maintenance drugs, a higher average price of $4.40 has been assumed. This higher price of $4.40 is based on (a) the fact that, at least in 1966, prescription prices for maintenance drugs were higher than those for nonmaintenance drugs,[13] and (b) the probability that some patients would find it advantageous to obtain a covered rather than an uncovered drug.[b]

Table 5

Estimated Average Prescription Cost for the Elderly in 1971 under Specified Assumptions[a]

Assumption	Average Cost per Prescription
No Medicare outpatient drug program	$4.30
Comprehensive outpatient drug program:	
—with no price control[b]	4.65
—with moderately effective price control[c]	4.00
—with very effective price control[d]	3.30

[a] Base: all prescribed drugs plus insulin. Limiting coverage to legend drugs only would increase the above averages by about 4 percent.

[b] This estimate is maximal.

[c] This cost is used generally in the cost estimates elsewhere in this chapter. It reflects the application of such techniques as an appropriately designed formulary, generic pricing, utilization review, and cost determination of vendor dispensing expenses, alone or in combination.

[d] This estimate is minimal. It reflects further application of such techniques as an appropriately designed formulary, generic pricing, government purchase, utilization review, and cost determination of vendor dispensing expenses, alone or in combination.

As noted above, the average prescription price could be reduced by the application of an appropriately designed formulary, generic pricing, government purchase, utilization review, and cost determination of vendor expenses, alone or in combination. The amount of reduction would depend on the degree to which these approaches might be applied—such as the nature of restrictiveness in the formulary, the scope of government purchase, and the extent of utilization review.

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[12] National Center for Health Statistics, U.S. Public Health Service: "Prescribed and Non-Prescribed Medications," Series No. 10, Number 39, U.S. Government Printing Office, Washington, D.C., 1967, p. 23.

[a] The *American Druggist* reported $3.49, while both the *Lilly Digest* and the *National Prescription Audit* reported $3.62.

[13] "The Drug Users," *op. cit.*, p. 35.

[b] For example, a covered drug carrying a market price of $5.00 might be obtainable for a co-payment of $1.00, and thus would be a better buy for a beneficiary than an uncovered drug with a market price of $2.00.

The Level of Drug Utilization

Benefit and administrative costs of a prescription drug insurance program would obviously be influenced by a number of variables that can affect the drug utilization of the average elderly person. Current utilization rates must therefore be adjusted to reflect the following:

FACTORS LIKELY TO INCREASE UTILIZATION

- Program awareness and lower out-of-pocket expenses for prescribed drugs, which will be manifest in (a) a reduction in the number of prescriptions written but not taken to a pharmacy for filling, and (b) a reduction in the number of prescriptions taken to a pharmacy and filled but not picked up.
- An increase in the number of physician visits per elderly person.
- The tendency of physicians to write more prescription orders per visit.
- A higher ratio of women to men in the elderly population. (The use of prescription drugs is generally higher among women.)[14]
- An increase in the average age of elderly people in the population. (Prescription drug use apparently increases with age.)[15]
- The growth of home health agency services, which would shift some drug consumption from an inpatient program (already covered under Medicare) to a new outpatient program.
- Possible controls on the quantity of medication prescribed per prescription.

FACTORS LIKELY TO RETARD INCREASES IN UTILIZATION—

- Appropriate utilization review.
- Financial deterrents applied by the program.
- Increased effectiveness of the drugs used.

The National Center for Health Statistics has estimated that the average person aged 65 or more acquired 11.4 prescriptions during fiscal year 1965.[16] (As noted elsewhere, the estimated average number of acquisitions for the elderly in calendar years 1967 was 13.6.)[17] Reference to demographic and drug survey data indicates that the 11.4 figure will rise to about 14 prescription acquisitions per person per year during 1971.[18] If it is further assumed that the introduction of a drug insurance program will in itself increase drug utilization by elderly individuals to the extent of approximately 7 percent, an estimate of 15 prescriptions per year is reached. (A program implemented without utilization review may result in about 16 prescriptions per capita per year, or a 15 percent increase in utilization.)

Thus, when an estimate of 15 acquisitions per year is related to the average number of 20.5 million persons expected to be eligible—as under Part A coverage—during 1971, it appears that a comprehensive program would involve about 308 million prescriptions during the first year of operation.

A different approach toward estimating prescription volume is indicated in Table 6. These figures are based on the total number of prescriptions for the entire population and the percentage of these that reflect prescriptions for the elderly as reported by various sources. The data, adjusted for 20.5 million persons at risk (approximately 200,000 of the elderly would not be eligible under Medicare) show that, without a program, the number of prescriptions would be approximately 24 percent of 1,393 million, or 328 million. If there were a 7-percent increase in utilization resulting from introduction of a drug insurance program, this number would be increased to more than 350 million.

In this chapter, it appears preferable to use the figure of 308 million, since its data base relies upon a more scientifically controlled sample and the results are corroborated by other studies.[19]

The foregoing considerations are summarized in Table 7, which indicates that the average number of acquisitions in a comprehensive program for the elderly in 1971 would range from about 12.5 to 16.0, depending on the effectiveness of utilization review.

Maintenance Drug Utilization. Utilization under a so-called maintenance-drug program would be more difficult to predict. Estimates for 1966 indicate that one-third to two-thirds of all prescription purchases by the elderly represented what may

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[14] "The Drug Users," *op. cit.*, p. 22.

[15] *Ibid.*, pp. 20–25.

[16] "Prescribed and Non-Prescribed Medicine," *op. cit.*, p. 27.

[17] "The Drug Users," *op. cit.*, p. 21.

[18] Rice, Dorothy P.; Anderson, Arne; and Cooper, Barbara S.: "Personal Health Care Expenditures of the Aged and Non-Aged, Fiscal Years 1966 and 1967," U.S. Social Security Administration, *Research and Statistics Note*, No. 11, June 14, 1968, Table 2.

[19] *Ibid.*

Table 6

Estimated Number of Prescriptions for All Age Groups and for the Elderly, 1964-1971

Year	Prescriptions Filled				
	All Age Groups			Elderly	
	Community[a] Pharmacies (millions)	Other[b] Vendors (millions)	Total[c] (millions)	Percent[c] for Elderly	No. for Elderly (millions)
1964	782. 4	106. 4	889. 0	19. 9	176. 9
1965	832. 6	139. 6	972. 2	21. 2	206. 1
1966	888. 3	176. 0	1, 064. 3	22. 3	237. 3
1967	930. 9	210. 5	1, 141. 4	23. 0	262. 5
1970 (Est.)	1, 072. 0	247. 0	1, 319. 0	----------	----------
1971 (Est.)	1, 124. 0	269. 0	1, 393. 0	23. 5	328. 0

[a] Derived from data published in the *American Druggist,* 1965–68.

[b] Derived from *Drug Topics* and other sources.

[c] Derived from Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, p. 21.

NOTE.—According to the National Center for Health Statistics survey in fiscal year 1965, the elderly accounted for 22.46 percent of the total prescription volume. (According to the *American Druggist* report for 1967, they accounted for 23 percent of the prescription volume in that year.) These data indicate that this proportion will rise to 24 percent in 1971, when the 20.7 million elderly will account for 334,000,000 prescriptions when using the base of 1,393,000,000 prescriptions for the entire population. Using different techniques, the methodology applied earlier indicates that the average elderly person will consume 14 prescriptions in 1971. Reference to a population base of 20.7 million indicates a prescription volume of 290,000,000.

be considered as maintenance drugs;[20] if a maintenance-drug program were instituted, with coverage provided for some products but not for others, there could be a significant shift in prescribing patterns, with physicians seeking to aid their patients by prescribing covered drugs in place of those excluded from the program.

In addition, under such a restricted program, there is a high probability that a significant number of ineligible claims would be submitted and paid. Some of these would be accurately reported, but would escape normal administrative detection. If the restrictions were excessively severe, there is a likelihood that ineligible products might be dispensed but reported as eligible drugs; here the records would appear to be correct, and the substitution could be detected only through costly and time-consuming audits.

Table 7

Estimated Number of Per Capita Out-of-Hotpital Prescriptions for the Elderly in 1971 under Specified Assumptions[a]

Assumption	Number of Prescriptions Per Capita
No Medicare outpatient drug program	14. 0
Comprehensive outpatient drug program:	
—with no utilization review[b]	16. 0
—with moderately effective utilization review[b] [c]	15. 0
—with effective utilization review[b]	14. 0
—with very effective utilization re-review[b]	12. 5

[a] Base: all prescribed drugs plus insulin. Limiting coverage to legend drugs only would reduce the above rates by approximately 8 percent.

[b] These estimates are *maximum* figures because rates would tend to be lowered by patient cost-sharing of at least $1.00 per prescription, and by the exclusion of anti-obesity drugs, multiple vitamins, etc.

[c] This rate is used generally in the cost estimates elsewhere in this chapter.

For these and related reasons, in estimating first-year utilization under a maintenance-drug program—even one restricted to coverage of only "important" maintenance drugs—it seems prudent to expect that utilization under such a limited program would be as much as 70 percent of that anticipated for a comprehensive program.

It may therefore be proposed that utilization under a comprehensive program with moderately effective utilization review would average 15.0 prescriptions per capita in 1971, while utilization under a maintenance-drug program would average about 10.5 prescriptions.

Distribution of Prescription Expenditures

Appreciation of drug expenditure distribution among the elderly would be vital in estimating the results of any annual deductible features. This distribution would be influenced by the impact of the following variables:

FACTORS RELATED TO THE INSURANCE PROGRAM

- The scope of drug coverage.
- The type and amount of patient cost-sharing.
- The effectiveness of utilization review.
- The extent of physician-dispensing.
- The growth of mail-order dispensing.

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[20] "The Drug Users," *op. cit.*, p. 35.

Factors Largely Beyond Program Control

- The change in the ratio of women to men in the elderly population.
- The change in the age distribution among the elderly.
- The change in the number of physician visits per elderly person.
- Any change in physician prescribing patterns involving (a) the number of prescriptions per patient visit, (b) the quantity of medication per order, (c) possible shifts to more or less expensive medications, and (d) possible shifts from uncovered to covered drugs in a maintenance-drug program.
- Any changes in prescription prices, involving (a) acquisition cost and (b) dispensing or overhead expenses.

Distribution data for per capita drug expenditure in 1962 and 1968, as developed from the results of a survey by the National Center for Health Statistics, are presented in Table 8, while estimates for 1971 are shown in Table 9.

From Table 8, it appears that 58 percent of the elderly had annual expenses of $25 or more for prescribed drugs in 1968, while over 38 percent had expenses of $50 or more. In Table 9, which includes projections for anticipated increases in utilization, it is estimated that 8.3 of 20.5 million individuals, or about 40 percent, would have expenses in excess of $50 in 1971. The figures in these tables will be important in considering the impact of various deductibles and cost-sharing features discussed below.

Distribution of expenses under a maintenance-drug program are difficult to predict. In general, it may be assumed that, as expenditure levels increase, the proportion of maintenance-drug users and the share of expenditures represented by maintenance drugs will increase. Thus, it is expected that maintenance drugs would account for 75 percent of all drug expenses in 1971. The proportion would rise to 79 percent for those with annual expenses over $25, 84 percent for those with expenses over $50, 90 percent for those with expenses over $75, and 97 percent for those with expenses over $100.

Table 8

Estimated Distribution of Elderly Persons by Size of Annual Prescription Drug Expenditures (in percent), 1962 and 1968

Annual Expenditure Per Capita	1962 [a]	1968 [b]
Total	100. 0	100. 0
None	28. 0	20. 0
$1 to $24	20. 0	21. 5
$25 to $49	19. 0	20. 0
$50 to $99	16. 0	19. 0
$100 and over	17. 0	19. 5

[a] Source: National Center for Health Statistics, U.S. Public Health Service: "Personal Health Expenses," U.S. Government Printing Office, Washington, D.C., 1965, p. 15, and personal communications. Derived by removal of cost for nonprescribed medications, equivalent to some 18 percent of total "medicine" expenditures per elderly person in 1962.

[b] Reflects impact of overall increase of prescriptions dispensed as indicated in Table 6, the increasing proportion of the population aged 65 and over, and the increasing per capita utilization of health services by the elderly noted since the inception of Medicare.

Table 9

Estimated Distribution of Elderly Persons by Size of Annual Prescription Drug Expenditures, 1971

Annual Expenditure Per Capita	Number of Individuals (millions)	Average Expenditures Per Category	Total Drug Expenditures (millions)	Number of Prescriptions Purchased (millions) [a]
Total	20. 5	--------	$1, 230	308
None	3. 9	-------	-------	-------
$1 to $50	8. 3	$27	222	56
$51 to $100	4. 5	73	327	82
$101 to $250	3. 1	151	467	117
$251 and over	0. 7	306	214	53

[a] Assumes an average expenditure of $4.00 per prescription in each category.

Note.—When considering deductible or co-payment provisions, the cost estimates to follow rely more on static than dynamic analysis. As such, the levels of utilization under such cost-sharing features may be overstated slightly. Yet, this may be prudent in that estimates based upon the *American Druggist* data indicate 350 million prescriptions might be expected rather than the 308 million figure calculated above. Similarly, projections from the 1967 estimates of "The Drug Users," *op. cit.*, indicate the purchase of 322 million prescriptions in 1971.

Administrative Expenses

The factors involved in administrative expenses have been discussed above in Chapter 6. There it was estimated that an administrative cost of 20 cents per prescription reimbursed could be expected during the first year under a very efficient program.

If annual deductibles should be used, the cost of assuring that the deductible was met must be added.

Administrative expenses per reimbursed prescription would be higher under a maintenance-drug program than under a comprehensive program.

Expenses would also be higher with a beneficiary-reimbursement approach than with a vendor-reimbursement system. In the following section, estimates are based on vendor reimbursement.

Program Cost Estimates

The following tables present a series of estimates on 1971 program costs involving various alternative approaches. They are based generally on the assumptions that the average price of a prescription would be $4.00, and that the average beneficiary would acquire 15 prescriptions per year. The cost figures shown in these tables could, as noted above, be reduced by application of an appropriately designed formulary, generic pricing, government purchase, utilization review, and the cost determination of vendor expenses.

Table 10 shows the effect on the numbers of beneficiaries and claims and the benefit expenses under a comprehensive program resulting from the use of different deductibles. With no deductible, the program would involve some 308 million claims and total benefits of $1,230 million (plus administrative expenses), all payable by the program. With a $25 deductible, there would be about 19 million claims ineligible for submission, 75 million submitted to meet the deductible requirements, and 214 million representing payable claims; these would involve $856 million (plus administrative expenses) payable by the program and $374 million payable by the beneficiaries—$74 million for claims ineligible for submission, and $300 million submitted to satisfy the deductible. With a $100 deductible, there would be 138 million claims ineligible for submission, 95 million submitted to meet the deductible requirements, and 75 million payable by the program; these would involve $301 million (plus administrative expenses) payable by the program and $929 million payable by the beneficiaries—$549 million for claims ineligible for submission, and $380 million submitted to satisfy the deductible.

In the foregoing, the so-called "prescriptions ineligible for submission" would be those purchased by beneficiaries who never did exceed the deductible amount during the year.

Table 11 illustrates the effect of different co-payment levels on program costs and patient expenses under a comprehensive program. In this instance, it is assumed that the program without any co-payment would involve benefit expenses of $1,230 million plus administrative expenses of $62 million, for a total of $1,292 million. With a co-payment of 50 cents, there would be a total cost to the program (including administrative expenses) of $1,138 million and total patient expenses of $154 million. These amounts would be $984 million for program costs and $308 million for patient expenses with a $1.00 co-payment; $831

Table 10

Effect of Specified Deductible Amounts on Number of Beneficiaries, Number of Claims, and Benefit Expenses under Comprehensive Drug Insurance, 1971 [a]

Deductible Amount	Number of Elderly (millions)			Number of Prescriptions (millions)			Prescription Expenses (millions)		
	With No Expense	With No Eligible Expenses	With Eligible Expenses	Ineligible for Submission	Submitted to satisfy Deductible	Payable as a Benefit	Ineligible for Submission	Submitted but not Payable	Payable as a Benefit
$0	3. 9	0	16. 6	0	0	308	$0	$0	$1, 230
$25	3. 9	4. 6	12. 0	19	75	214	74	300	856
$50	3. 9	8. 3	8. 3	56	104	148	222	415	593
$75	3. 9	10. 8	5. 8	97	109	102	387	435	408
$100	3. 9	12. 8	3. 8	138	95	75	549	380	301

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[a] Assumes 20.5 million persons at risk with an average of 15 prescriptions per year which show an average cost of $4.00 per item.

million for program costs and $461 million for patient expenses with a $1.50 co-payment; and $677 million for program costs and $615 million for patient expenses with a $2.00 co-payment.

Table 11

Estimated Program and Patient Expenses under Comprehensive Drug Insurance with Different Co-Payment Levels, 1971

[In millions] [a] [b]

Co-Payment	Program Costs		Patient Expense
	Benefit Expense	Total Cost [c]	
None	$1, 230	$1, 292	
$0.50	1, 076	1, 138	$154
0.75	999	1, 061	231
1.00	922	984	308
1.25	846	908	384
1.50	769	831	461
1.75	692	754	538
2.00	615	677	615

[a] The cost figures in this table are based on the assumed average values of $4.00 per prescription, and the acquisition of 15 prescriptions per capita per year.

[b] These cost figures could be reduced by use of approaches discussed on page 75.

[c] Assumes a $62 million administrative cost (20 cents per prescription) as is believed to be obtainable under a very efficient vendor payment system.

NOTE.—This static analysis does not reflect (1) the likelihood that as co-payment increases, utilization will be somewhat reduced; (2) to the extent co-payment is set high enough to omit some prescriptions from benefits, the average price of the reimbursed prescriptions will be higher than that for all prescriptions, and (3) the dynamic consequences of flat dispensing fee allowances.

The effect of different co-insurance percentage levels is indicated for the same comprehensive program in Table 12. Here, for example, there would be program costs (including administrative expenses) of $1,169 million and patient expenses of $123 million with 10-percent co-insurance; and program costs of $677 million and patient expenses of $615 million with 50-percent co-insurance.

Table 13 illustrates a different approach to indicating the effects of deductibles, but including different levels of administrative expense which could be expected with different deductible levels. Thus, it is assumed here that administrative expenses would be $62 million with no deductible, $82 million with a $25 deductible, and $51 million with a $100 deductible.

Table 12

Estimated Program and Patient Expenses under Comprehensive Drug Insurance with Different Co-Insurance Levels, 1971

[In millions] [a] [b]

Co-Insurance	Program Costs		Patient Expense
	Benefit Expense	Total Cost [c]	
None	$1, 230	$1, 292	
10%	1, 107	1, 169	$123
20%	984	1, 046	246
25%	924	986	306
50%	615	677	615

[a] The cost figures in this table are based on the assumed average values of $4.00 per prescription, and the acquisition of 15 prescriptions per capita per year.

[b] These cost figures could be reduced by use of approaches discussed on page 75.

[c] Assumes a $62 million administrative cost (20 cents per prescription), as is believed to be obtainable under a very efficient vendor payment system.

NOTE.—This static analysis does not reflect (1) the probability that utilization is likely to be reduced somewhat as the co-insurance amount approaches the 50% figure; and (2) the dynamic consequences of flat dispensing fee allowances.

The impact of a deductible and a co-payment used in combination for both a comprehensive program and a maintenance-drug program is shown in Table 14. The examples here include deductibles of 0, $50 and $100, and co-payments of $1.00, $1.50, and $2.00, respectively. It is evident, for example, that the costs for a limited maintenance-drug program under certain cost-sharing provisions are close to those for a comprehensive program under other cost-sharing methods. Thus, the benefits paid under a comprehensive program with a $2.00 co-payment and no deductible would be $615 million, compared with $653 million for a maintenance-drug program with a $1.00 co-payment and a $50 deductible. Similarly, the benefits paid under a comprehensive program with a $1.50 co-payment and a $50 deductible would be $630 million, compared with $609 million under a maintenance-drug program with a $1.50 co-payment and no deductible.

In all the above calculations, it is assumed that patient cost-sharing would be limited to the deductible, co-payment, or co-insurance as indicated, and that no patient would be required to pay an additional amount to meet the difference between

Table 13

Estimated Program and Patient Expenses under Comprehensive Drug Insurance with Different Deductible Levels, 1971

[In millions] [a] [b]

Deductible	Program Costs: Benefit Expense	Program Costs: Total Cost [c]	Patient Expense
None	$1, 230	$1, 292	
$25	856	938	$374
$50	593	668	637
$75	408	471	822
$100	301	352	929

[a] The cost figures in this table are based on the assumed average values of $4.00 per prescription, and the acquisition of 15 prescriptions per capita per year.

[b] These cost figures could be reduced by use of approaches discussed on page 75.

[c] Assumes a very efficient system of vendor payment which results in an average administrative cost of 20 cents per claim paid. A conservative sum for administering the deductible provision has been added, when indicated. (Patient reimbursement is used often when deductibles are featured and under such conditions the estimates shown must be trebled.) Administrative expense with different deductible levels is estimated as follows:

	(Millions)
No deductible	$62
$25 deductible	82
$50 deductible	75
$75 deductible	63
$100 deductible	51

NOTE.—This static analysis does not reflect the likelihood that utilization will decrease and that certain claims will not be charged against the program as the deductible amount increases. However, co-payment or co-insurance on a per prescription base would not increase these estimates.

Table 14

Effect of Combined Deductible and Co-Payment upon Alternative Program Features in Terms of Prescriptions Submitted, Benefit Payments, and Patient Expense, 1971.[a] [b]

Deductible	Co-Pay	No. of Prescriptions Submitted [c] (millions): Comp. [d]	No. of Prescriptions Submitted [c] (millions): Maint. [e]	Benefits Paid (millions): Comp.	Benefits Paid (millions): Maint.	Patient Expense (millions): Comp.	Patient Expense (millions): Maint.
$0	$1. 00	308	210	$922	$714	$308	$516
	1. 50	308	210	769	609	461	621
	2. 00	308	210	615	504	615	726
$50	1. 00	252	192	756	653	474	577
	1. 50	252	192	630	557	600	673
	2. 00	252	192	504	461	726	769
$100	1. 00	170	150	226	219	1, 004	1, 011
	1. 50	170	150	189	183	1, 041	1, 047
	2. 00	170	150	151	146	1, 079	1, 084

[a] The cost figures in this table are based on the assumed average values of $4.00 per prescription, and the acquisition of 15 prescriptions per capita per year.

[b] These cost figures could be reduced by use of approaches discussed on page 75.

[c] Includes prescriptions submitted for satisfaction of deductible.

[d] Comprehensive drug program.

[e] Limited maintenance drug program.

any allowance established by the program and the charge actually set by the vendor.

It should be recognized that a reimbursement formula based on flat dispensing fee allowances for vendor services may generate patient pressures calling for increases in the amount of medication per prescription. For example, a patient might seek to get a prescription for 500 tablets, but involving a single co-payment expenditure, rather than a prescription plus four refills for 100 tablets apiece, also totaling 500 tablets but involving a total of five co-payment expenditures. This situation would be most likely to occur with maintenance drugs needed for chronic illness rather than with drugs required for an acute illness. If this should occur, it is likely that there would be (1) increases in product costs per prescription, (2) a decrease in the average number of prescriptions per capita, and (3) an eventual increase in the dispensing fee allowance to vendors.

These changes would probably be most significant under a program with a relatively large co-payment per prescription—such as $2.00 or more. In the long run, however, under a program invoking effective utilization review, such tendencies would probably produce a lower program cost per unit of medication.

It should also be recognized that all of the cost estimates shown here assume a moderate degree of cost control. With very tight controls—including competitive pricing, use of a formulary excluding unnecessary products, etc.—the average prescription price under a comprehensive program could be $3.30 rather than the $4.00 assumed in the tables presented earlier in this chapter. Similarly, utilization could be lower if utilization review were "effective" rather than "moderately effective." Under these assumptions, a cost estimate for a comprehensive program in 1971 might be $947 million for benefit expense—$660 million with a $1.00 co-payment per prescription—instead of the $1,230 million indicated in Tables 10 to 12.

On the basis of the staff estimates developed in Chapter 9, if eligibility were set at age 70 and all prescription drugs were covered, the cost of the benefit and the claims levels—assuming a $1 co-payment—would be reduced by about 30 percent. If the eligibility age were set at 72, benefit cost and claims levels under this type of program would be reduced by over 41 percent (see Table 15.)

Alternative Cost Estimates

Additional cost estimates for a prescription drug program, relying upon quite different assumptions, have been developed and are presented in Appendix A. The basis for the observed differences in the two approaches, and for the generally higher costs noted in the appendix, stem in large part from different assumptions involving the average number of prescriptions per capita per year, the extent of utilization review, the possible or probable changes in physician prescribing patterns, the average prescription prices resulting from program reimbursement policies, the extent of maintenance drug coverage, and other factors.

Table 15

Estimated 1971 Drug Utilization and Benefit Cost under $1 Co-Payment Insurance Program

Age Group	Number of Persons (millions)	Rx's per Capita	Total Rx's (millions)	Benefit Expense (millions)	Patient Expense (millions)
65–69 [a]	7. 1	13. 0	92	$275	$92
70–71 [b]	2. 4	14. 5	35	105	35
72 and over	11. 0	16. 5	181	542	181
All elderly	20. 5	15. 0	308	922	308

[a] Persons aged 65 through 69 would account for 29.9 percent of 1971 program costs.

[b] Persons aged 70 and 71 would account for nearly 11.4 percent of 1971 program costs.

APPENDIX A

ANALYSIS OF ALTERNATIVE COST ESTIMATES[a]

Cost estimates were prepared for two basic proposals: (1) coverage of all legend drugs (and a few exceptions such as insulin) and (2) coverage of a restricted list of maintenance drugs, limited initially to a specific list, each subject to 20-percent co-insurance. The costs of a number of other proposals covering all legend drugs or maintenance drugs involving different types of cost-sharing (but with benefits of approximately 75 to 85 percent of total charges) were derived by adjusting these basic cost estimates, as summarized in Table A–6.

The cost estimates assume that benefits would be payable only to persons aged 65 or older. The estimates are presented in terms of the level-cost of the various proposals under the Hospital Insurance part of Medicare (Part A), which is financed through payroll contributions. Estimated level-costs are determined on the same 25-year basis as in all other Hospital Insurance cost estimates, but they apply only to the period from 1971 on (since benefits would begin in 1971). These level-costs are based on the taxable payroll arising under the Hospital Insurance program if the maximum taxable earnings base is $7,800 per year in all future years. Where appropriate, estimates are also given of the cost in calendar year 1971 under the Supplementary Medical Insurance part (Part B) of the Medicare program.

It should be noted that the cost estimates with respect to maintenance drugs represent estimates of the cost of covering a specific list of drugs. The list consists essentially of those drugs which, according to the Master Drug List,[b] were dispensed to the aged for an average of 90 days of therapy or more in 1966. While the Master Drug List is merely an index of current prescribing habits, and does not necessarily reflect expert medical judgments as to what is good drug therapy or what drugs are most significant for treatment of serious illness, nor would it necessarily be identical with a list of covered maintenance drugs drawn up for purposes of a drug benefit under Medicare, the list is considered to provide an adequate basis for a preliminary estimate of benefit costs under a maintenance drug program. (The cost estimates for any maintenance drug proposal would, of course, vary with the actual initial list of drugs to be covered under the program.)

Summary of Principal Assumptions Employed in Cost Estimates

The cost estimates are presented in terms of "high" and "low" cost estimates. It should be noted that the per capita annual costs shown in the cost estimates increase at higher rates after 1971 for the proposals covering all drugs than do those for the maintenance drug programs (more in each case under the high-cost estimate than under the low-cost estimate). The lower rate of increase in both the average price and utilization of the latter results in a level-cost for the maintenance drug programs that is about one-third of that for the programs covering all drugs, in contrast to the 1971 costs, for which the ratio is about one-half.

The assumptions employed in the estimates of the costs of the basic proposals appear in Table A–1. A short explanation of the most important of these assumptions follows:

1. *Utilization in 1967*. The principal sources of data were:

   (i) The *National Prescription Audit*, Gosselin Associates.

   (ii) The *American Druggist* estimates of total prescriptions and of the proportion of prescriptions used by persons aged 65 or older.

   (iii) The National Health Survey, National Center for Health Statistics, Series 10, No. 33.

   (iv) The Current Medicare Survey, Social Security Administration.

The level of utilization indicated by these surveys for persons aged 65 or older ranges from approximately 11 to 13 prescriptions per capita. Since the basic utilization figures from which the estimates were derived are all based on survey information rather than on data derived from an actual insurance program, the actual level of utilization that would occur under any of the proposals could vary substantially from the estimates. The information available is thought to be of higher quality than that available for the original estimates for the Supplementary Medical Insurance program (which resulted in a premium rate that was 7 percent low).

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[a] Prepared in the Office of the Actuary, Social Security Administration.

[b] Task Force on Prescription Drugs: "The Drug Users," U.S. Government Printing Office, Washington, D.C., 1968, pp. 31 *et seq.*

2. *Long-Run Increase in Drug Utilization.* As the full resources of medical technology are extended to a greater proportion of the population, the average consumption of drugs increases. The long-run rate of increased use of drugs is approximately 2 to 3 percent per year, although the rate of increased use of drugs has been much higher in recent years, due in part to Federal programs. The average rate of increase in the future should be slightly higher than 2 to 3 percent, assuming an accelerated pace of discovery generated by Federal research funds. The rate of increased use of maintenance drugs has been much less than for all drugs, and this trend is expected to continue in the future.

3. *Increase in Utilization Due to Third-Party Payment of 75 to 85 Percent of Cost.* Payment by a third party of 75 to 85 percent of the cost of medical services generally results in a substantial increase in utilization. For example, utilization of hospital services by the population aged 65 and over increased by 20 to 25 percent after passage of the Hospital Insurance program, despite the presumption that there is relatively little voluntary element in whether a person is hospitalized. Due to the increased discretionary element in prescription purchases, the increase in drug utilization should be substantially more. This phenomenon can be explained as a decrease in the supply curve by 75 to 85 percent at each point. Even with very inelastic demands, a substantial increase in quantity must be anticipated.

4. *Substitution.* The drugs in the list of maintenance drugs on which cost estimates are based are those which are frequently prescribed for use on a continuous or recurrent basis in the treatment of chronic illnesses which afflict the aged. If only maintenance drugs were covered under Medicare, it is contemplated that once a drug was included in the list of covered drugs, payment would be made without regard to the specific condition for which the drug was prescribed. It is assumed, therefore, that payment would be made, in some situations, for drugs prescribed to treat acute illness, rather than chronic illness. It is also assumed that there would be a degree of substitution in the prescribing of drugs within the therapeutic categories represented by the drugs in the maintenance list; that is, a physician would prescribe a covered drug in lieu of a noncovered drug. However, since the drugs on which the cost estimates are based can be characterized as having undesirable or even dangerous effects if used by persons who are not suffering from the specific conditions for which the drugs are intended, it is assumed that substitution of such drugs would be strictly limited.

5. *Exclusion of Nonlegend Drugs.* The basic utilization data pertain to all drugs acquired with a physician's prescription. Approximately 13 percent of such drugs, however, could be acquired legally without a prescription. Each of the proposals excludes such "nonlegend" drugs from coverage, and the net result of this exclusion is a reduction in total cost of approximately 6 percent.

6. *Average Prescription Price in 1967.* Nearly all basic data show an average prescription price for all prescribed drugs of around $4.00 per prescription in 1967.

7. *Long-Run Increase in Average Price per Prescription.* Several series of data concerning the average price of a prescription are available: *The National Prescription Audit*, the *American Druggist*, the *Lilly Digest*, and the Consumer Price Index. The first three series are averages of all prescriptions sold in each year, and each shows a steady progression to higher prices, with the increases averaging 2 to 3 percent a year in recent years.

The Consumer Price Index shows the average price of a consistent group of drugs. As new discoveries become widely used, representative new drugs are substituted for drugs of declining importance, but since the new drugs represent an improvement in quality, the index is adjusted so as not to reflect the higher price of the new drugs. Thus, the index reflects only price changes which occur after inclusion of a drug in the index. The increasing average price of all prescriptions sold results not from price increases of individual drugs, however, but rather from the introduction of new drugs, set at prices higher than the previous average. The Consumer Price Index reflects the decrease that has occurred, on the average, in the prices of drugs after introduction, due primarily to the expiration of patents.

It is assumed that the average increase in prescription prices for all prescribed drugs will be somewhat less in the future than over the past decade, due primarily to: (1) legislation requiring that new patents for drugs represent significant discoveries, and (2) the anticipated expiration of more than the average number of patents on drugs used frequently by persons aged 65 or over.

The average annual price increase in the maintenance drug categories has been less than the average for all drugs, and this trend is expected to continue in the future. The average annual increase in price for the list of maintenance drugs assumed in the cost estimates would permit modest substitution of new discoveries for older drugs, provided that the average price of existing drugs remains constant, as it has in recent years (as measured by the Consumer Price Index of Prescription Prices.) Continuing inflationary economic conditions would prevent such substitution. (There is no allowance in the proposal covering all legend drugs for continuing inflationary conditions.)

In estimating the cost of the maintenance drug proposals, it was assumed that any change in the list of covered drugs over the 25-year period covered by the cost estimates would be such that any increase in the cost of the program would be within the allowance provided for new drugs (see Table A–1, Item B.2 (ii)). (It is assumed that if a drug benefit based on coverage of only maintenance drugs were adopted, an independent actuarial review would be made of any contemplated changes in the list; if the changes would adversely affect the actuarial status of the program, such changes would be made only if additional financing were provided; quite obviously, if the law did not unambiguously provide for an independent actuarial review before such substitution is possible, the cost estimates would be substantially higher.)

8. *Population.* All estimates are based on the population projections of the Office of the Actuary, Social Security Administration. According to these projections, for 1971, 19.5 million persons would be covered under the Supplementary Medical Insurance proposals, and 20.5 million persons would be covered under Hospital Insurance. Of the 20.5 million persons, 18.8 million would be insured under the Hospital Insurance program; the remainder would have their benefits paid through appropriations from the General Fund of the Treasury.

9. *Co-Insurance.* In the event that 20-percent co-insurance were incorporated in a proposal for which cost estimates are presented without such a feature, the cost estimates would be reduced by somewhat more than 20 percent, since utilizations would be reduced.

Cost of Insurance Plans Involving an Initial Deductible

The cost of plans involving an initial deductible were obtained by adjusting the estimates for the basic plans covering all legend drugs and maintenance drugs. The "low-cost" and "high-cost" assumptions are taken from the extremities of the range of values for each variable which appear reasonably likely. They do not represent the lowest costs or highest costs possible, but are similar to confidence limits, based on thorough examination of available pertinent information. Costs for proposals which involve an initial deductible were calculated only on an "expected" basis—i.e., using the means of the distributions of possible values for the variables (the equivalent of point estimates). Low-cost and high-cost estimates were computed using ratios to a similar estimate of the cost of the basic proposal to cover all drugs.

Cost of Insurance Plans Involving Payments per Prescription

Imposition of a fixed amount of cost-sharing per prescription will alter the relationship between initial and renewed prescriptions, as those covered by the program attempt to avoid paying the charge when a prescription is renewed by persuading their physician to allow an adequate quantity on the initial prescription. The larger the payment, the smaller will be the percentage of renewals (presently 65 percent of all prescriptions). Another consequence of the attempt to avoid renewals will be a certain amount of over-purchasing, when a patient who purchased a large enough quantity to avoid a renewal finds that a renewal would have been unnecessary. It is assumed that such prescribing of increased quantities takes place despite all possible administrative actions designed to prevent it, including enforcement of a provision limiting any prescription to a 90-day supply.

The assumptions used for each payment amount and the resulting intermediate costs (i.e., average of the low-cost and high-cost assumptions) are summarized in Table A–6. The cost of any combination of deductible and payment may be obtained by (1) applying the ratio in Item (8) of Table A–6 to the basic utilization model (Item 1 of Table A–2), and (2) multiplying by Item II. 7 of Table A–4.

It was also assumed in the derivation of costs for plans involving payments per prescription that (1) reimbursement would be made according to a formula based on an allowance for wholesale costs and a fixed professional fee (so that relatively few prescriptions are eliminated even by a $3.00 payment) and (2) pharmacists obtain the same average compensation per prescription that they do at present.

Administrative Expenses

The cost estimates in the following tables do not include administrative costs.

Under all alternatives, a wide variation is possible in administrative expenses, depending upon how the plan will be administered (including the philosophy underlying program administration, such as the emphasis placed on the gathering of statistical information concerning prescribing practices of physicians, drug utilization by patients, and the cost of manufacture, distribution, and retailing of medicines).

For the maintenance drug proposals, under an administrative system designed to pay benefits as expeditiously as possible, with sufficient controls to prevent all fraud and abuse which it is economical to prevent, the administrative cost would be about $50 to $80 million for 1971 (level-cost of 0.01 to 0.02 percent of taxable payroll). The costs under an administrative system using source data equipment located in drugstores and placing great emphasis on controls over patients, doctors, and drugstores and on collection and analysis of data of all sorts, producing high costs but not the maximum possible, would be about $200 to $450 million for 1971 (level-cost of 0.05 to 0.10 percent of taxable payroll), depending on the extent and complexity of data collected and administrative controls employed.

The minimum administrative costs for the proposals covering all legend drugs, without an initial deductible, are somewhat higher—about $100 to $160 million in 1971 (level-cost of 0.02 to 0.04 percent of taxable payroll). The cost of elaborate administrative systems would increase less proportionately than for a minimal administrative system. due to the high fixed cost elements of electronic data processing systems and programs, and would be in the range of $300 to $700 million in 1971 (level-cost of 0.08 to 0.16 percent of taxable payroll).

The cost of minimal administrative systems for the proposals involving initial deductibles are less than if all drugs were covered, provided that patients are reimbursed and no assignments are permitted: the percentage decreases in mimimal administrative expenses would be approximately half the decrease in benefit costs. The administrative expenses for the two Montoya amendments which are considered here [a] would be moderately higher than for the $25-deductible, 20-percent coinsurance plan (due to higher utilization, resulting from absence of cost-sharing and the carry-over deductible). Again a wide variation is possible, depending on the type of administrative system followed. The cost of a mimimal administrative system for the Montoya amendments could be as low as $80 to $130 million in 1971 (level-cost of 0.02 to 0.03 percent of taxable payroll). It should be noted that if a benefit were to be provided under Supplementary Medical Insurance without at least a $25-deductible provision, administrative costs would be significantly higher than for the same benefits financed through Hospital Insurance. Under any of the proposals, a requirement that drugstores accept the reimbursement allowance and designated cost-sharing as total compensation would add significantly to administrative costs.

Changes in Cost Estimates for Montoya Amendment of 1967

The cost estimates for the amendment offered by Senator Montoya in the Senate consideration of the Social Security Amendments of 1967 on November 16, 1967 (Amendment No. 440),[a] which was not adopted, are higher than those previously issued by the Office of the Actuary, Social Security Administration, due to their being for a later period and to the availability of new information from a number of sources, which has led to revision of a number of the assumptions used in the previous estimates (such as a lower allowance for the exclusion of nonlegend drugs and also a much lower allowance for paying benefits on the basis of the lowest-priced chemical equivalent).

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[a] See Appendix B.

Senator Montoya introduced a revised proposal in 1968 (S. 2936), which had significantly lower costs (primarily because of containing a 20-percent co-insurance element). Its cost closely approximates that of the proposals of the type considered in this report with a $25 initial deductible and 20-percent co-insurance (see Item II. 2 in Table A–4 for the annual per capita cost—$38.47). This amendment has a slightly higher cost because of containing a carry-over deductible provision, but has offsetting lower costs for certain other reasons.

Table A–1

Summary of Basic Assumptions

Item	All Legend Drugs		Maintenance Drugs	
	Low	High	Low	High
A. Utilization (prescriptions per capita per year):				
1. 1967 level, no insurance program	11	13	5. 3	6. 2
2. Long-run increase in drug utilization (annual) (percent):				
(i) 1967–71	3	5	1	2
(ii) 1971–95	3	3	1	2
3. Changes in utilization due to insurance program (percent):				
(i) Increase in utilization due to third-party payment of 75–85 percent of cost	25	40	2	8
(ii) Substitution prescribing of maintenance drugs as substitutes for noncovered drugs			5	10
(iii) Reduction of free samples furnished by physicians	2	4	2	4
4. Definition of covered drugs:				
(i) Adjustment for inclusion of insulin, 1967 level	. 6	. 7	. 6	. 7
(ii) Adjustment for exclusion of nonlegend drugs (percent)	−13	−13		
B. Average prescription price:				
1. 1967 level	$4. 00	$4. 00	$4. 40	$4. 40
2. Long-run increase in average price per prescription (percent):				
(i) 1967–71	2	2	½	1
(ii) 1971–95	1	2	½	1
3. Payment ceiling based on cost of lowest price generic alternative of acceptable quality (percent)	−5	−2	−5	−2
4. Adjustment for exclusion of nonlegend drugs	+8	+8		

Table A–2

1971 Benefit Cost per Capita According to Basic Utilization Assumptions

Item	Utilization (acquisitions per capita)		Average Price (per acquisition)		Total Benefit Cost (per capita)	
	Low-cost	High-cost	Low-cost	High-cost	Low-cost	High-cost
A. Coverage of all drugs:						
(1) Utilization model [a]	14.5	21.5	$4.44	$4.58	$64.40	$98.45
(2) Cost-sharing of 20 percent					51.50	78.75
(3) Charge per prescription: [b]						
(a) $1					55.40	84.70
(b) $2					51.50	78.75
(c) $3					50.10	76.80
B. Coverage of maintenance drugs:						
(1) Utilization model [a]	6.7	9.2	4.26	4.48	28.55	41.20
(2) Cost-sharing of 20 percent					22.85	32.95
(3) Charge per prescription: [b]						
(a) $1					24.25	35.00
(b) $2					21.15	30.50
(c) $3					18.85	27.20
(d) $3 new, $1.50 renewal					19.00	27.75
(e) $3 new, $1 renewal					19.10	27.90
(f) $2 new, $1 renewal					21.45	31.00

[a] Potential benefit costs; utilization would be approximately 17½ percent higher without 15–25 percent cost-sharing.

[b] Assumes limit of a 90-day supply per prescription.

Table A–3

Summary of Basic Assumptions Pertaining to Proposals With an Initial Deductible

	Initial Deductible				
	None	$25	$50	$75	$100
A. Utilization (prescriptions per capita per year):					
1. 1967 level, no insurance program	12	12	12	12	12
2. Long-run increases in drug utilization (annual) (percent):					
(i) 1967–71	4	4	4	4	4
(ii) 1971–95	3	3	3	3	3
3. Changes in utilization due to insurance program (percent):					
(i) Increase in utilization due to third-party payment of 75–85 percent of cost (applies after deductible satisfied)	32	24	20	20	20
(ii) Reduction in free samples furnished by physicians	3	1	1	0	0
4. Definition of covered drugs (percent):					
(i) Adjustment for inclusion of insulin	5	5	5	5	5
(ii) Adjustment for exclusion of nonlegend drugs	−13	−13	−13	−13	−13
B. Average prescription price:					
1. 1967 level	$4	$4	$4	$4	$4
2. Long-run increase in average price per prescription (percent):					
(i) 1967–71	2	2	2	2	2
(ii) 1971–95	1½	1½	1½	1½	1½
3. Payment ceiling based on lowest price generic alternative (of acceptable quality) (percent)	−5	−5	−5	−5	−5
4. Adjustment for exclusion of nonlegend drugs (percent)	8	8	8	8	8

Table A-4

Summary of Derivation of Cost Estimates of Plans With Initial Deductibles and Cost Sharing[a]

I. Utilization model (assuming no insurance program):

A. Distribution of annual charges per capita:

	Charges for Prescriptions					
	$0	$1-25	$25-50	$50-75	$75-100	$100+
(1) Frequency, persons in category (percent)	23	25	16	11	7	18
(2) Average charges for persons in category	0	$12. 00	$37. 00	$62. 00	$87. 00	$194. 00
(3) Cost per capita for category	0	$3. 00	$5. 90	$6. 80	$6. 10	$35. 00

B. Cumulative distribution of annual charges per capita:

	Deductible				
	None	$25	$50	$75	$100
1) Percentage with charges greater than deductible (frequency of potential claim)	77	52	36	25	18
(2) Charges for persons with charges greater than deductible (charges of potential claimants)	$56. 80	$53. 80	$47. 90	$41. 10	$35. 00
(3) Deductible	0	13. 00	18. 00	18. 75	18. 00
(4) Charges in excess of deductible	56. 80	40. 80	29. 90	22. 35	17. 00
II. Cost of insurance program paying approximately 75 to 85 percent cost:					
1. Change in utilization due to insurance program, factor	1. 35	1. 24	1. 20	1. 20	1. 20
2. Charges per capita under insurance program, net of deductible	$76. 68	$50. 59	$35. 88	$26. 82	$20. 40
3. Allowance for underfiling	0	2. 50	2. 15	1. 70	1. 35
4. Charges submitted for reimbursement less deductible	76. 68	48. 09	33. 73	25. 12	19. 15
5. Co-insurance (20 percent)	15. 34	9. 62	6. 75	5. 02	3. 83
6. Benefit cost of program	61. 34	38. 47	26. 98	20. 10	15. 32
7. Ratio to cost of no-deductible program (percent)	100	63	44	33	25

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[a] All dollar figures are annual costs per capita in 1971.

Table A–5

Summary of Derivation of Cost Estimate for Montoya Amendment of 1967[a]

(Amendment No. 440)

1. Charges of those meeting deductible, if no insurance program	$56.90
2. Deductible ($25, less "carry-over")	13.00
3. Charges after deductible (item 1 minus item 2)	43.90
4. Factor to account for change in utilization due to insurance program—approximately 6 percent cost-sharing (due to payment only for lowest-priced generic alternative)	1.39
5. Charges per capita under insurance program, net of deductible (item 3 times item 4)	61.02
6. Allowance for underfiling	2.50
7. Carry-over deductible	.50
8. Charges submitted for reimbursement, less deductible (item 5 plus item 7 minus item 6)	59.02
9. Reduction due to available lower priced generic alternative [b]	3.54
10. Annual cost of benefits under Montoya Amendment (item 8 minus item 9)	55.48

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[a] All figures except item 4 are annual costs per capita in 1971.

[b] This amendment would have allowed the deductible to be satisfied by the full charges paid, irrespective of a lower priced generic alternative. It is assumed that prescriptions would satisfy the deductible in order by date of purchase.

Table A–6

Summary of Derivation of Cost Estimates for Proposals Involving Payments per Prescription [a]

	All Legend Drugs Payment			Maintenance Drugs Payment		
	$1	$2	$3	$1	$2	$3
(1) Benefit cost, basic utilization model [b]	$81.40	$81.40	$81.40	$34.80	$34.80	$34.80
(2) Increase in charges due to prescribing larger quantity than required (percent)	3	7	[c] 12	2	3	4
(3) Total charges per capita (1971)	$83.85	$87.10	$91.15	$35.50	$35.85	$36.20
(4) Decrease in number of prescriptions (see text) (percent)	20	35	45	25	35	45
(5) Number of prescriptions per capita	14.4	11.7	9.9	6.0	5.2	4.4
(6) Cost-sharing:						
(a) Prescriptions less than cost-sharing payment:						
(i) Number of prescriptions per capita	0	0	[c] 1.7	0	0	0
(ii) Average cost per prescription	$0	$0	$2.65	$0	$0	$0
(iii) Cost per capita	$0	$0	$4.50	$0	$0	$0
(b) Cost-sharing payments per capita	$14.40	$23.40	$24.60	$6	$10.20	$13.20
(c) Total cost-sharing per capita	$14.40	$23.40	$29.10	$6	$10.20	$13.20
(7) Benefits per capita	$69.45	$63.70	$62.05	$29.50	$25.65	$23.00
(8) Ratio to basic utilization model [b]	.85	.78	.76	.85	.74	.66

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[a] All dollar figures relate to the annual cost per capita in 1971.

[b] Average of low-cost and high-cost figures in Item 1 of Table A–2.

[c] Applies to prescriptions costing more than $3.00.

Table A–7

Estimated Level-Cost of Benefits for Persons Insured Under the Hospital Insurance Program (as Percentage of Taxable Payroll) for Various Drug Benefit Proposals

Cost-sharing provisions	All Legend Drugs		Maintenance Drugs	
	Low-Cost	High-Cost	Low-Cost	High-Cost
1. 20 percent co-insurance:				
(1) No deductible	.32	.56	.10	.18
(2) $25 deductible	.20	.35		
(3) $50 deductible	.14	.25		
(4) $75 deductible	.11	.18		
(5) $100 deductible	.08	.14		
2. $1 payment per prescription:				
(1) No deductible	.34	.60	.09	.19
(2) $25 deductible	.22	.38		
(3) $50 deductible	.15	.27		
(4) $75 deductible	.12	.19		
(5) $100 deductible	.09	.15		
(6) No deductible, coverage at age 70	.24	.42		
(7) No deductible, coverage at age 72	.20	.36		
3. $2 payment per prescription:				
(1) No deductible	.32	.56	.11	.17
(2) $25 deductible	.20	.35		
(3) $50 deductible	.14	.25		
(4) $75 deductible	.11	.18		
(5) $100 deductible	.08	.14		
4. $3 payment per prescription:				
(1) No deductible	.31	.55	.10	.15
(2) $25 deductible	.20	.34		
(3) $50 deductible	.14	.24		
(4) $75 deductible	.11	.18		
(5) $100 deductible	.08	.14		
5. Initial/Renewal payment per prescription:				
(1) $3/$1.50			.09	.15
(2) $3/$1.00			.09	.15
(3) $2/$1.00			.10	.17
6. Montoya Amendment of 1967	.29	.52		
7. Montoya Amendment of 1968	.20	.35		

Table A–8

Estimated 1971 Benefit Costs of Various Drug Benefits Proposals (Benefit Costs for Insured and Uninsured Persons Combined)[a]

Cost-sharing Provisions	All Legend Drugs		Maintenance Drugs	
	Low-Cost	High-Cost	Low-Cost	High-Cost
	(millions)		(millions)	
1. 20 percent co-insurance:				
(1) No deductible	$1,060	$1,615	$470	$675
(2) $25 deductible	670	1,015		
(3) $50 deductible	465	710		
(4) $75 deductible	350	535		
(5) $100 deductible	265	405		
2. $1 payment per prescription:				
(1) No deductible	1,135	1,735	495	720
(2) $25 deductible	715	1,095		
(3) $50 deductible	500	765		
(4) $75 deductible	375	575		
(5) $100 deductible	285	435		
(6) No deductible, coverage at age 70	795	1,245		
(7) No deductible, coverage at age 72	680	1,070		
3. $2 payment per prescription:				
(1) No deductible	1,055	1,615	435	625
(2) $25 deductible	665	1,015		
(3) $50 deductible	465	710		
(4) $75 deductible	350	535		
(5) $100 deductible	265	405		
4. $3 payment per prescription:				
(1) No deductible	1,045	1,575	385	560
(2) $25 deductible	660	990		
(3) $50 deductible	460	695		
(4) $75 deductible	345	520		
(5) $100 deductible	260	395		
5. Initial/Renewal payment per prescription:				
(1) $3/$1.50			390	570
(2) $3/$1.00			390	570
(3) $2/$1.00			440	635
6. Montoya Amendment of 1967	950	1,460		
7. Montoya Amendment of 1968	670	1,015		

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[a] Approximately 91 percent of amounts relate to benefits financed by the Hospital Insurance Trust Fund; the other 9 percent would be appropriated from general revenues.

Table A-9

Prescriptions on the Basis of Which Some Payment Made in 1971 (Prescriptions for Insured and Uninsured Persons Combined)[a]

Cost-sharing Provisions	All Legend Drugs		Maintenance Drugs	
	Low-Cost	High-Cost	Low-Cost	High-Cost
	(millions)		(millions)	
1. 20 percent co-insurance:				
(1) No deductible	295	430	135	190
(2) $25 deductible	195	280		
(3) $50 deductible	130	190		
(4) $75 deductible	95	140		
(5) $100 deductible	70	100		
2. $1 payment per prescription:[b]				
(1) No deductible	235	350	95	135
(2) $25 deductible	150	230		
(3) $50 deductible	105	155		
(4) $75 deductible	75	115		
(5) $100 deductible	55	80		
(6) No deductible, coverage at age 70	160	240		
(7) No deductible, coverage at age 72	140	205		
3. $2 payment per prescription:[b]				
(1) No deductible	190	285	80	115
(2) $25 deductible	125	185		
(3) $50 deductible	85	125		
(4) $75 deductible	60	95		
(5) $100 deductible	45	65		
4. $3 payment per prescription:[b]				
(1) No deductible	160	240	65	95
(2) $25 deductible	105	155		
(3) $50 deductible	70	105		
(4) $75 deductible	50	80		
(5) $100 deductible	40	55		
5. Initial/Renewal payment per prescription:[b]				
(1) $3/$1.50			70	100
(2) $3/$1.00			70	100
(3) $2/$1.00			85	120
6. Montoya Amendment of 1967	200	300		
7. Montoya Amendment of 1968	165	280		

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[a] Approximately 91 percent relate to persons insured under the Hospital Insurance program.

[b] Number of prescriptions are artificially reduced by prescribing and purchasing of larger quantities to avoid paying co-payment for renewals.

APPENDIX B

SUMMARY OF AMENDMENT NO. 440 TO H.R.12080 (MONTOYA AMENDMENT)[a]

Amendment No. 440 would have established a Formulary Committee consisting of the Surgeon General of the Public Health Service, the Commissioner of the Food and Drug Administration, and the Director of the National Institutes of Health, which would have determined what drugs would be covered under the program; the Committee would have been assisted by an advisory group that represented national organizations of physicians, drug manufacturers, pharmacists, experts in public health, hospital pharmacists, medical schools, pharmacy schools, and consumers. The amendment stated that the list of covered drugs could include, in addition to drugs which require a prescription for dispensing, lifesaving drugs which do not require a prescription; no other guidelines were given as to what drugs should be included. Drugs would have been listed by their established name, and where applicable, by a proprietary name.

In addition to determining which drugs should be covered, the Formulary Committee would have established and published the "allowable expense" with respect to each drug included in the list. In establishing the "allowable expense" the Committee would have been guided by the acquisition cost to the ultimate dispenser for the most frequently prescribed quantities of a given drug plus a dispensing fee. In a case where the drug was available by generic name as well as by proprietary name, the "allowable expense" would have been the lowest cost at which the drug was available in a form which the Formulary Committee found to be of acceptable quality. Regional variations in acquisition cost would have been taken into account. Reimbursement would have been made directly to the beneficiary, or to the person to whom he assigned his benefit. There would have been an annual deductible of $25 with respect to drugs, in addition to the deductible under present law with respect to expenses for services covered under Part B other than drugs. Only the cost of drugs covered by the program could have been counted toward the $25 drug deductible. The amount reimbursed would have been the lower of the "allowable expenses" or the actual price paid for the drug. The allowable expense with respect to any drug would have been established by the Formulary Committee. The Secretary would have been able to use carriers to help in the administration of the program. The cost of the drug benefit under the bill has been estimated to be $2.30 per month in addition to the premium for other medical insurance benefits, with a matching amount paid out of general revenues.

(A similar bill, S. 2936, introduced by Senator Montoya on February 6, 1968, differs from this amendment in several respects. Under S. 2936, the amount reimbursed would be the lower of the "allowable benefit" or 80 percent of actual expenses incurred for the purchase of qualified drugs; in addition, all prescription drug expenses incurred could be counted toward meeting the drug deductible. Reimbursement would not be made for the first claim submitted in any one year unless the actual expense exceeded the deductible, or for a subsequent claim unless the actual expense for the claim was $10 or more; in determining the allowable benefit, the Secretary would give consideration to the costs of overhead and a fair profit; and the composition of the Formulary Committee and the Advisory Group differ slightly from Amendment No. 440.)

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[a] Introduced in the Senate on November 16, 1967.

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